EXHIBIT I

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

Master File No. 2:12-MD-02327
MDL 2327
JOSEPH R. GOODWIN, U.S. DISTRICT JUDGE

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

This document relates to the cases listed below:

Mullins, et al. v. Ethicon, Inc., et al.	2:12-cv-02952
Sprout, et al. v. Ethicon, Inc., et al.	2:12-cv-07924
Iquinto v. Ethicon, Inc., et al.	2:12-cv-09765
Daniel, et al. v. Ethicon, Inc., et al.	2:13-cv-02565
Dillon, et al. v. Ethicon, Inc., et al.	2:13-cv-02919
Webb, et al. v. Ethicon, Inc., et al.	2:13-cv-04517
Martinez v. Ethicon, Inc., et al.	2:13-cv-04730
McIntyre, et al. v. Ethicon, Inc., et al.	2:13-cv-07283
Oxley v. Ethicon, Inc., et al.	2:13-cv-10150

(CAPTION CONTINUED ON FOLLOWING PAGE)

VIDEOTAPED DEPOSITION OF
STEVEN B. MACLEAN, Ph.D., P.E.
September 29, 2015

Atkins, et al. v. Ethicon, Inc., et al. 2:13-cv-11022
Garcia v. Ethicon, Inc., et al. 2:13-cv-14355
Lowe v. Ethicon, Inc., et al. 2:13-cv-14718
Dameron, et al. v. Ethicon, Inc., et al. 2:13-cv-14799
Vanbuskirk, et al. v. Ethicon, Inc., et al. 2:13-cv-16183
Mullens, et al. v. Ethicon, Inc., et al. 2:13-cv-16564
Shears, et al. v. Ethicon, Inc., et al. 2:13-cv-17012
Javins, et al. v. Ethicon, Inc., et al. 2:13-cv-18479
Barr, et al. v. Ethicon, Inc., et al. 2:13-cv-22606
Lambert v. Ethicon, Inc., et al. 2:13-cv-24393
Cook v. Ethicon, Inc., et al. 2:13-cv-29260
Stevens v. Ethicon, Inc., et al. 2:13-cv-29918
Harmon v. Ethicon, Inc., et al. 2:13-cv-31818
Snodgrass v. Ethicon, Inc., et al. 2:13-cv-31881
Miller v. Ethicon, Inc., et al. 2:13-cv-32627

(CAPTION CONTINUED ON FOLLOWING PAGE)

Matney, et al. v. Ethicon, Inc., et al. 2:14-cv-09195
Jones, et al. v. Ethicon, Inc., et al. 2:14-cv-09517
Humbert v. Ethicon, Inc., et al. 2:14-cv-10640
Gillum, et al. v. Ethicon, Inc., et al. 2:14-cv-12756
Whisner, et al. v. Ethicon, Inc., et al. 2:14-cv-13023
Tomblin v. Ethicon, Inc., et al. 2:14-cv-14664
Schepleng v. Ethicon, Inc., et al. 2:14-cv-16061
Tyler, et al. v. Ethicon, Inc., et al. 2:14-cv-19110
Kelly, et al. v. Ethicon, Inc., et al. 2:14-cv-22079
Lundell v. Ethicon, Inc., et al. 2:14-cv-24911
Cheshire, et al. v. Ethicon, Inc., et al. 2:14-cv-24999
Burgoyne, et al., v. Ethicon, Inc., et al. 2:14-cv-28620
Bennett, et al., v. Ethicon, Inc., et al. 2:14-cv-29624

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Videotaped deposition of STEVEN B. MACLEAN, Ph.D., P.E., held at the offices of Butler Snow LLP, 1170 Peachtree Street, Suite 1900, Atlanta, Georgia, on Tuesday, September 29, 2015, at 9:42 a.m., pursuant to Agreement before Michelle M. Boudreaux, a Registered Professional Reporter in the State of Georgia.

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Videographer: Josh Coleman

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THE VIDEOGRAPHER: We are now on the record. My name is Josh Coleman. I'm the videographer for Golkow Technologies. Today's date is September 29th, 2015. The time is approximately 9:42 a.m.

This video deposition is being held in Atlanta, Georgia in the matter of In Re Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation for the United States District Court of the Southern District of West Virginia, Charleston Division. The deponent is Dr. Steve B. MacLean.

If counsel will please introduce themselves for the record.

MR. THORNBURGH: Dan Thornburgh for the plaintiffs.

MR. MORRIS: Brandon Morris for the plaintiffs.

MR. HUTCHINSON: Chad Hutchinson, counsel for Ethicon and Johnson & Johnson.

THE VIDEOGRAPHER: The court reporter is Michelle Boudreaux and will now swear in the witness.

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STEVEN B. MACLEAN, Ph.D., P.E., being first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. THORNBURGH:

Q Good morning, Doctor.

A Good morning.

Q Dr. MacLean, is that -- am I pronouncing it correctly?

A You are.

Q Doctor, I'm going to mark as Exhibit No. -- well, first off, you understand my name is Dan Thornburgh and I represent the plaintiffs in this litigation, right?

A I do.

Q All right. And you understand that there are 37 plaintiffs?

A I do.

Q Okay.

MR. THORNBURGH: And go ahead and mark as Exhibit No. 1 the notice of deposition.

Q (By Mr. Thornburgh) While she's going that, Doctor, did you bring any documents with you -- oh, I'm sorry, she can't -- she can't write and type at the same time.

(Discussion off the written record.)

(Exhibit 1 marked for identification.)

Q (By Mr. Thornburgh) Did you bring any documents with you responsive to the deposition notice?

A I did. It was actually in electronic form, but, yes, I did.

Q Okay. I also see some --

MR. HUTCHINSON: Counsel, you got a copy for me?

MR. THORNBURGH: Yeah. Sorry. I figured you'd have the notice.

Q (By Mr. Thornburgh) I see that there are some notebooks stacked up behind you over here. What are in those notebooks?

A I have three notebooks I brought with me today. The first notebook that's in front of me consists of my two reports that were submitted in this matter, as well as a few select documents from the seven-year dog study at the back of the notebook.

And then to my left on the ground, I have two additional notebooks. One is the set of documents that consists of the microcrack committee documents from the 1980s that was furnished by counsel. And then I have a series of select documents from production as a separate notebook.

Q Okay. So let's go ahead and do a couple things. I'm going to mark as Exhibit No. 2 the notebook that you have in front of you, which is your expert report and some select documents from the dog study --

A That's correct.

Q -- is that correct?

A That is correct.

(Exhibit 2 marked for identification.)

Q (By Mr. Thornburgh) And then we will mark as Exhibit No. 3 a second binder, which says "Deposition Materials, September 29th, 2015."

(Exhibit 3 marked for identification.)

Q (By Mr. Thornburgh) And this -- what's contained -- briefly, what's contained in this Exhibit No. 3?

A So briefly, there are select documents from the universe of produced documents in the matter, as well as expert reports for a few of the plaintiffs' experts.

Q Okay.

A And this, by the way, is all duplicative to

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what's going -- what I'm going to hand you on this thumb drive.
Q Okay, we'll get to the thumb drive in a minute.
A Sure.
Q As Exhibit No. 4, we'll mark a binder that is titled "1980s Microcrack Committee Documents."
(Exhibit 4 marked for identification.)
Q (By Mr. Thornburgh) Okay. And then Exhibit -- I see that you have two thumb drives over there.
A I do.
Q Okay, so --
A One is for you, plaintiffs, and one is for defense. They're identical.
(Exhibit 5 marked for identification.)
Q (By Mr. Thornburgh) Okay. And what's contained within the thumb drive?
A All -- my entire case file.
Q And we'll get to it in more detail in a little bit, but I did see that you had some -- as part of your expert report, you had conducted some studies or analyzed some studies of degraded polypropylene -- pristine mesh or pristine Prolene that was degraded

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either chemically or through ultraviolet radiation?
A That's correct.
Q Okay. And did you conduct those studies?
A I did. Those studies were done at my direction.
Q Okay. My question was did you conduct those studies, not whether or not it was done at your --
A Those studies were conducted by Exponent, me and some staff, as well as a third-party laboratory.
Q Okay. And did you bring with you the underlying data from those studies?
A I did.
Q Is that contained within Exhibit No. 5?
A Yes, it is.
Q And what underlying data do you have related to those studies that were conducted at Exponent?
A You have the universe of photographs and images and micrographs that we took on all of the tested specimens, you have a log that details each specimen that was tested, and you also have the testing protocols that we used at the lab.
Q Okay. There's an envelope behind you.
A Yes, there is.
Q What's in the envelope?

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A The envelope used to contain the two thumb drives that I just presented to you.
Q Okay. Is there anything written on the envelope --
A Nothing.
Q -- front or back?
A Nothing.
Q Okay. All right, so let's set these out of the way of the video. Put them right here for now, okay?
A Sure, fine.
Q We'll refer to them as we go throughout the day, and if you need to refer to any item within those exhibits, just feel free to pick up an exhibit and refer to it.
A Will do.
Q You also have a bag, a plastic clear bag. What's contained within the plastic clear bag?
A It's an exemplar TVT mesh.
MR. THORNBURGH: We'll mark that as Exhibit No. 6.
(Exhibit 6 marked for identification.)
Q (By Mr. Thornburgh) Is it just an exemplar TVT?

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A It is, correct.
Q Did you bring invoices with you today?
A I did.
Q Are they also contained within the thumb drive?
A They are.
Q And you're getting paid $355 per hour; is that correct?
A Exponent is charging 355 for my time, correct.
Q And how much have you invoiced to the defendants to date?
A Through our current billing cycle, we have about $100,000 billed.
Q And you say "current." Current up until what date?
A That would have been an invoice that would have included all charges through August.
Q Okay, through August. So now we're here in almost October.
A Yes.
Q Have you done additional work since August?
A We have.
Q Okay. How much additional time have you

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spent either preparing for this case or for this deposition?
A I don't know. That bill has not been generated yet.
Q Approximately, a fair -- just give me a fair estimation.
A I can give you a fair estimate of my time. Probably in the order of 30 to 40 hours.
Q Okay. At 340?
A Three fifty-five.
Q Three fifty-five?
A Correct.
Q And you said you can give me a fair estimate of your hours. Were there other people that were involved?
A Yes.
Q How many other people were involved in the work that was performed at Exponent while preparing for this deposition?
A I would estimate there's been three to five additional people, associate staff, working on the matter. The bills will reflect the exact people and their times.
Q Okay. If you turn to Exhibit No. 1 and go to

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page 4, which is the Schedule 4 -- or Schedule A, which are a list of documents that were requested as part of the deposition notice. A copy -- we asked for a copy of your up-to-date CV. I know that there's a CV, a resume, attached as an appendix to your expert report. Has it been updated since you served the expert report?
A It has not.
Q And does the thumb drive, Exhibit No. 5, contain your entire file?
A It does.
Q Does it contain your entire underlying data?
A It does.
Q You had indicated earlier that some of the testing was outsourced to another lab.
A Correct. The histology staining was done at a third-party lab.
Q Okay. And what lab was that?
A It's a lab called Histion. They are in Everett, Washington.
Q Do you have the -- all of the underlying data that was generated by Histion?
A Yes.
Q -- Laboratories?
A Yes, we do.

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Q And is that contained within Exhibit No. 5?
A Yes, it is.
Q Who conducted or performed the scanning electron microscopy?
A Of which?
Q Of the chemical -- chemically oxidized pristine exemplar and the ultraviolet radiation exemplar.
A Dr. Benight did that at my direction. B-E-N-I-G-H-T.
Q And is Dr. Benight an employee of Exponent?
A She is.
Q She is. And did she maintain laboratory notebooks?
A She maintained records of all her work, yes, correct.
Q Did she maintain laboratory notebooks?
A I'm not sure if it's in notebook form, but any -- anything that needed written down, as she produced those micrographs, was written down.
Q You've written some articles or have a history of analyzing -- or ensuring that good laboratory practices are followed?
A What are you referencing?

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Q Well, do you follow -- do you know what I mean by "good laboratory practices," GLP guidelines?
A I'm sorry, I thought you were mentioning a -- or referencing a specific --
Q Let me ask the question again.
A Sure.
Q Do you know what good practices are?
A Sure, yes.
Q GLP --
A Yes.
Q -- guidelines? And the GLP guidelines require that laboratory notebooks are maintained, correct?
MR. HUTCHINSON: Object to form.
THE WITNESS: They can.
Q (By Mr. Thornburgh) They do, correct?
A Depending on the nature of the work, yes, they can.
Q Well, for scanning electron microscopy work?
A All of the records that were -- excuse me. All of the information that was needed to verify and confirm the work that she -- that she had done on the SEM has been documented.
Q She didn't maintain a GLP lab notebook,

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correct?
A Without asking her, I'm not quite sure.
Q So you don't know, sitting here today, whether or not she maintained a GLP notebook?
MR. HUTCHINSON: Object to the form. Been asked and answered, Counsel. Move on.
THE WITNESS: Same answer.
Q (By Mr. Thornburgh) Did you ask her?
A I don't recall if I asked her. Look, these are -- these are micrographs that have all of the information contained on the micrograph. So if there was additional notes that she took in terms of sample preparation and things like that, which would be customary, I'd expect them to be available. But we can walk through the micrographs, and I can certainly explain to you exactly everything that was done.
Q In Exhibit 5, you did not produce any lab notebooks that were or may have been maintained by Dr. Benight, correct?
A I would have to go back and look in the thumb drive to confirm that answer.
Q Did you maintain a lab notebook?
A I did not. I did not see a need to do any of that on my end.

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Q We'll get to that in greater detail in a little bit.
A Uh-huh.
Q You -- strike that.
Request No. 16 asks for all documents or communications relating to presentations or lectures given or contributed to by you which concerned pelvic mesh, pelvic organ prolapse, or stress urinary incontinence. Do you have or have you participated in any presentations or lectures concerning pelvic mesh, pelvic organ prolapse, or stress urinary incontinence?
A No.
Q Did the defendants or defense counsel ask you to assume any facts in this litigation?
A They did not.
Q Let's look at your expert report briefly. I think it's Exhibit No. 2. Is that your full report?
A Yes.
Q Does it include your CV?
A It does.
Q You started working for -- well, strike that.
Just give us a little brief background, where you went to college, where you attended your -- where

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you attended your postgraduate studies, please.
A Okay. I graduated from Rensselaer Polytechnic Institute in Troy, New York as a undergraduate in mechanical engineering in 1993. I went on to pursue a master's degree in mechanical engineering and received that in 1997. I then went on to study polymer science and engineering at Rochester Institute of Technology at the master's level and graduated in 2001. And then I received my Ph.D. in material science with a focus on polymer science and engineering in 2007.
Q What did you do after your education?
A I guess it depends on which education component you're speaking of, but I --
Q After your master's.
A So let me just work you -- walk you through my employment history. So after I graduated from Rensselaer in 1993, I started working for GE Aerospace, which ultimately got divested to Lockheed Martin, in kind of a classic mechanical -- mechanical engineering aerospace world.
And then from there, I went back to GE and went to GE Plastics in 1996, and I was with that company through 2011, which includes the last four

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years of a divestiture to a company call SABIC, S-A-B-I-C. Same business, just different nameplate outside. And in 2011, I came to Exponent.
Q What was your title at -- I think you said GE Aerospace. Is that correct?
A I was a mechanical engineer.
Q Okay. And what was your role?
A I was designing, analyzing, and testing mechanical systems for defense contract work, U.S. government military work.
Q And when you say "mechanical engineering and analyzing and testing mechanical systems," what do you mean by "mechanical systems"?
A Large military weapons and guns, ballistic missile systems that are on Trident submarines, things of that nature.
Q Okay. And when did you -- eventually you transitioned from GE Aerospace to GE Plastics?
A That's correct.
Q And what year was that again?
A It was somewhere between 1995 and 1996.
Q And what was your job title at GE Plastics?
A I had several roles at GE Plastics. My entry-level job there or -- excuse me. The job that I

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first obtained when I started with that business was called plastics design and analysis leader. And then I held a number of increasingly -- a number of jobs with increasing responsibility up until the time I left.

Q So plastic design and?

A And analysis leader.

Q And what did that job entail?

A Working with customers that were buying, specifying, using our resins in all sorts of different types of applications and markets.

Q And when did that job -- when -- did you transition at some point from the plastic design and analysis leader to another job at GE Plastics?

A I did.

Q And what -- when was that?

A That was in approximately 1998.

Q And what was that job title?

A I went on to be a senior application development engineer, which is a field engineer, for the company.

Q Senior application development engineer?

A That's right.

Q And you said it's a field engineer. What does that mean?

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A You're in the field, so you're not working in an office per se, you're in the field. You have a region or territory, and you're technically servicing the customers in that region or territory that are buying and specifying your resin.

Q And when did that -- you did that from 1998 until what year?

A Approximately 2001.

Q Okay. And what did you do from -- after 2001?

A In 2001, I became a technical manager with the business.

Q And what did that job entail as a technical manager?

A I was managing an engineering staff that had a number of different responsibilities.

Q Like what?

A We did root cause investigations. We did specification work for customers that were buying our resins. We would do testing. We would look at the processing of our materials in a number of different applications. And we also had -- my team had a regulatory agency component to it where we would interface with a lot of bodies and agencies that

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develop standards for the plastics industry.

Q How long did you do that?

A I did variants of that job up until I left in 2011. The team got a little bit bigger and larger at times; it became more of a global role over time. So it kind of developed in size and responsibility, but it was essentially the same role.

Q Is it fair to say that as a senior application field engineer at GE Plastics, that you were -- you said you were in the field. Were you selling resins; is that what your job title was?

A No, it was not -- it was not selling resins. So we had customers that were buying our resins locally, and I would visit with them routinely if they had failure issues, if they had technical specification questions, if they wanted to know how our materials could be processed in their processing equipment. So that's converting raw pellets to plastics either through injection molding, thermoforming, extrusion, things of that nature. So it was a technical role supporting our customers to help them convert our raw materials into their finished molded articles.

Q And as the technical manager after your senior application field engineering position ended,

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that also dealt with resins?

A Yes, correct.

Q And you were the managing -- you were managing staff in that position who were determining the root cause of failures of resins that GE Plastics was selling?

A Failures of applications that used our materials, correct.

Q What do you mean by "failures of applications that used our materials"?

A Well, we've got customers that are taking our raw material and converting it into a plastic component. Sometimes that plastic component goes out to the field, it cracks, it underperforms, it doesn't do what its intended use is supposed to do, and we would help our customers in many instances, help them understand why that material was underperforming -- or why that device in our material was underperforming.

I failed to mention that somewhere in there, I did a black-belt role. Just remembered it off the top of my head. I spent two years as a black belt for the company in between the field job and the technical manager role.

Q Okay. And what does it mean to be a black

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belt?
A Black belt is a title that's designated to our quality teams. It's based on the Six Sigma methodology and principles where you use statistical tools to analyze business processes and then make improvements with statistical significance.
Q What types of business processes were you analyzing?
A We -- a lot of different processes. Anything from manufacturing processes to improved productivity in resin manufacturing, all the way through to processes and testing that we were doing at some of our manufacturing facilities.
Q If we just turn to your expert report, which is Exhibit No. 2, you have a -- after the "Limitations" page on 6, page 7, you have sort of your biography.
A Correct.
Q If you go to -- actually, go to page 8. It says, "Prior to joining Exponent in 2011." Do you see that, the second paragraph on page 8?
A I do.
Q Okay. It says that you have a variety of technical roles of increasing responsibilities. Throughout your tenure, you were routinely involved in

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material selection, performance, and testing for, among other things, high-demand applications, product safety assessment, and product failure analysis. As a result, you state that you have significant experience and expertise with industry standards and applicable regulations that prescribe the technical performance of polymeric materials in end-use applications, including those in the medical device industry.
A That's correct.
Q What medical device applications were you involved with in that 15-year period at General Electric Plastics or SABIC Innovative Plastics?
A There's too many to list and remember. I can give you a snapshot of what I can remember.
Q Sure. What do you remember?
A First thing I remember is that selling resin into the healthcare and medical device market was a focus market for the business, so we would sell millions of pounds of material annually to applications that were servicing medical device and healthcare applications. That's first thing.
Applications that I remember off the top of my head would be trocar tubes, syringes, cannulas, CPAP devices, sleep apnea masks, flexible hosing and tubing

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for IV and fluid deliveries, stopcocks, rigid fittings in fluid delivery systems, scalpels, a number of different dental applications, catheters. I think those are the ones that I recall right now.
Q None of those are permanent implantable medical devices, correct?
A None of them -- well, catheter, you could make an argument it has some implantation to it. And that actually was work that I did -- the one that I'm thinking of most vividly is work I did at Exponent. The other implant that I've worked on is a tongue retractor implant at Exponent.
Q Okay. So you worked on a tongue retractor medical device implant. Was that a permanent medical device?
A It was.
Q And what's a tongue retractor?
A It's basically a silicone rubber stud that gets passed through the tongue, it affixes to the floor of your oral cavity, and it prevents your tongue from falling back to your throat when you're sleeping.
Q So you said tongue retractor, and what was the other permanent implantable medical device?
A Catheters, catheters that go into the body

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for extended periods of time. I've worked on several of those, both on failure analysis as well as some proactive work, for some clients at Exponent.
Q Neither of -- neither the tongue retractor nor the catheter would be implanted underneath the submucosa, correct? Wouldn't be implanted under the skin, correct? A catheter is inserted, right?
A It goes through the skin. I mean --
Q But it doesn't embed into the skin, correct?
A It doesn't embed into the skin, that's correct.
Q And neither does the tongue retractor, correct?
A Correct. It's in the mouth.
Q What medical device companies did you work with during your 15 years at General Electric Plastics?
A Oh, I'm not sure I can actually give that information. That would be considered confidential. But you can be assured that it's several of the brand-name medical device companies that are out there.
Q Did you work with Johnson & Johnson?
A I can't give you that information.
Q Did you work with Ethicon?
A It's the same answer. It's confidential. I

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can't tell you what specific customers we sell to.
Q Did you sell any resins that were being used for permanent implantable mesh devices?
A Could you repeat that?
Q When you were involved in your 15 years at General Electric and SABIC, did you sell any resins to any medical devices [sic] who were using the resin to manufacture polypropylene pelvic organ mesh devices?
A Not that I'm aware of. But let me just add to that that sometimes we do not have direct line of sight to where our resin ultimately ends up. And what I mean by that is we sell -- our direct sales are to molders and converters, who then sell molded parts to end-users and specifiers. So if you look at the supply chain, we don't always know where every single pellet that we manufacture ends up in the marketplace.
Q You don't know one way or the other whether or not you ever worked on a resin product that was distributed or sold to a manufacturer who was using that resin to manufacture polypropylene medical devices, correct?
A That's correct. I don't know for sure, correct.
Q In this biography that you have, you sort of

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generally talk or generically talk about polymers and polymeric materials, but you don't ever once reference polypropylene.
A Polypropylene is a thermoplastic material that is similar or identical to the resins that we were manufacturing at GE. I can break that down if you need me to.
Q Okay. So the resins that you were manufacturing at GE were not polypropylene, correct?
A At the time of GE, correct. When we were -- when we were purchased by SABIC in 2011, the answer is incorrect. Polypropylene was part of our portfolio. And, actually, I have to go back even further. There was an L&P acquisition by GE Plastics in the mid 2000 time frame, which also included polypropylene as a base resin.
Q What do you mean by "base resin"? Was it a co-polymer of some sort?
A It could be. In many instances, our L&P business was compounding specialty resins, so you take a base polymer like polypropylene and you would incorporate carbon fillers, glass fillers, mica, glass bead, things of that nature, to enhance properties.
Q For what type of application would those have

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been?
A Again --
Q What are specialty resins that use polypropylene as a base and then inject carbon filler, glass -- mica, glass bead, and things of that nature?
A Automotive applications come to mind right away. Something that you're looking for high strength, high stiffness, good chemical resistance, those would be all the properties that that type of formulation brings to the table.
Q In fact, most of your polymer science background has been with the automotive applications, correct?
MR. HUTCHINSON: Object to the form.
THE WITNESS: No, not true.
Q (By Mr. Thornburgh) What other applications?
A Again, over 20 years, too many to remember, but I'll give you a broad-brush. Fluid engineering, fluid handling, electrical devices and enclosures and components, medical, healthcare, automotive, consumer electronics, consumer devices, aerospace.
Q After you left SABIC, you joined Exponent?
A Correct.
Q And that was in 2011?

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A That's correct.
Q And you joined Exponent to help out with litigation that Exponent was hired by industry manufacturers; is that correct?
A No.
MR. HUTCHINSON: Object to form.
THE WITNESS: No. I joined Exponent to become a consultant to polymer science engineering.
MR. THORNBURGH: Go ahead and mark as Exhibit No. 7 a FAPSIG newsletter.
(Exhibit 7 marked for identification.)
Q (By Mr. Thornburgh) Do you know what FAPSIG is?
A I do.
Q What is it?
A Failure Analysis and Prevention Special Interest Group.
Q What's the Failure Analysis and Prevention Special Interest Group?
A It's a section within the Society of Plastics Engineers.
Q And is that a society that Exponent belongs to?

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A It's a society that employees from Exponent belong to.
Q I'll hand you Exhibit No. 7. And this is dated May of 2012. Do you see that?
A I do.
Q If you go to the sixth page, under "Announcements," do you see your picture there --
A I do.
Q -- at the very top?
A I do.
Q It says -- and right above that, it says, "Exponent is pleased to announce the addition of three experienced consultants to its polymer science and material chemistry practice." Do you see that?
MR. HUTCHINSON: Excuse me, Counsel, you've given me your marked-up --
MR. THORNBURGH: Oh.
MR. HUTCHINSON: -- you have inadvertently given me your --
MR. THORNBURGH: Sorry.
MR. HUTCHINSON: -- marked-up copy. Just why don't you trade out with me for the one you have in your hand.
MR. THORNBURGH: Sure. There you go.

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Q (By Mr. Thornburgh) So, "Exponent is pleased to announce the addition of three experienced consultants in its polymer science and materials chemistry practice, as well as the expansion of Exponent's presence in Atlanta, Georgia and China." Do you see that?
A I do.
Q Okay. And it says -- it's got your name there. It gives a little bit of history about you. And it says, "Dr. MacLean" -- that's you, right --
A That's correct.
Q -- "will draw from his expertise in advanced high-performance thermoplastics, structure/property relationships, and suitability for material selection to perform litigation and nonlitigation failure analyses and assist industry clients with product development." Did I read that accurately?
A You did.
Q And does that accurately depict your role at Exponent?
A I'd say it depicts work that I perform at Exponent, correct.
Q You were hired by Exponent, in fact, according to this document, to help Exponent perform

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litigation services for industry clients, right?
A Correct.
Q Like Ethicon?
A Correct.
Q Like Johnson & Johnson?
A Correct.
Q Now, I've been calling you a doctor, but you're not a medical doctor, correct?
A That's correct.
Q You're not a urogynecologist, correct?
A Correct.
Q You don't hold yourself out as a medical doctor or an expert in medical science, correct?
A Correct.
Q You don't hold yourself out as a urogynecologist?
A Correct.
Q You're not a veterinarian?
A Correct.
Q You're not a toxicologist?
A Correct.
Q And you don't hold yourself out as an expert in toxicology, correct?
A Correct.

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Q You're not a pathologist?
A Correct.
Q And you're not an expert in pathology or histopathology analysis, correct?
A Correct.
Q You don't have any patents concerning polypropylene medical devices, correct?
A I do not.
Q You're not an expert in the design of polypropylene mesh devices, correct?
A I have not designed a mesh device.
Q You won't be offering opinions in this case concerning the proper design of polypropylene mesh devices, correct?
MR. HUTCHINSON: Object to form. Counsel, he's already given you his opinions in his expert report.
MR. THORNBURGH: I get to ask the questions.
MR. HUTCHINSON: Sure.
Q (By Mr. Thornburgh) You're not going to be offering opinions concerning -- for example, you're not going to offer opinions about whether the pore size in the TVT mesh is an adequate pore size, correct?

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A I'm not giving mesh design -- mesh design with regards to pore size opinions.
Q And you're not going to offer opinions concerning the -- whether or not the weight of the polypropylene mesh used in the TVT is an adequate weight?
A Correct.
Q You're not going to offer opinions about whether or not the TVT elicits an excessive, unacceptable, inflammatory response --
A Correct.
Q -- as a design of those features, correct?
A That is correct.
Q You're not an infectious disease doctor, correct?
A Correct.
Q You're not go to offer any opinions regarding infection and polypropylene materials in the TVT?
A I am not.
Q Other than in this litigation, have you ever consulted with a medical device manufacturer concerning the design of a mesh implant?
A Could you repeat that one?
Q Other than in this litigation, have you ever

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consulted with any medical device manufacturer concerning the design of a polypropylene mesh implant?
A No, I have not.
Q You've never observed the implantation of surgical mesh, correct?
A I actually have.
Q On video?
A On video.
Q One of Ethicon's training videos?
A I believe so.
Q Let me ask a better question. You've never observed the implantation of surgical mesh devices prior to your involvement in this litigation, correct?
A That's correct.
Q And this is the first case where you've ever testified as an expert regarding polypropylene material that was implanted in human beings? Let me ask -- strike that. Let me ask a better question.
This is the first case where you have testified as an expert regarding polypropylene material that is intended to be implanted in human beings?
A That's correct.
Q Prior to your involvement -- well, strike that.

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You've never analyzed explanted polypropylene mesh, correct?
A Analyzed? No, but I've reviewed the analysis of explanted meshes at length for this matter.
Q Let me ask a better question.
A Uh-huh.
Q Prior to this matter, prior to Butler Snow's lawyers hiring you as an expert in this case, you've never analyzed explanted polypropylene mesh, correct?
MR. HUTCHINSON: Object to form.
THE WITNESS: That's correct.
Q (By Mr. Thornburgh) Have you ever performed any pre-clinical testing of polypropylene mesh implants prior to this case?
A I have not.
Q You're not a pre-clinical scientist?
A I am not a pre-clinical scientist.
Q You're not going to offer opinions concerning pre-clinical studies that were performed by Ethicon?
A If it includes biocompatibility assessment that I've reviewed, it will -- it will depend on your questions regarding biocompatibility.
Q You didn't perform any biocompatibility assessments of the TVT mesh device, correct?

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A Correct.
Q So you're telling me that you may offer opinions concerning the biocompatibility assessment of TVT?
A No opinions, but we may walk through the biocompatibility documents that I've reviewed.
Q You've never conducted any pre-clinical studies yourself, right?
A Correct.
Q You've never looked at medical devices that were explanted from animals --
A Correct.
Q -- to determine whether or not it was biocompatible?
A Correct.
Q Your only experience reviewing biocompatibility testing has been in this case, correct?
A No, not true.
Q Okay. What biocompatibility -- sorry, let me -- let me ask a better question.
Your only experience in analyzing the biocompatibility of the Prolene used in the TVT device has been in this case, correct?

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A Correct.
Q You've never performed any post-market testing of mesh implants prior to this case, correct?
A Correct.
Q Have you ever performed a failure analysis of a polypropylene mesh device prior to this litigation?
A For mesh, no, but I've done scores of failure analysis with polyolefins and polypropylenes.
Q What medical device have you performed a failure analysis that contained polypropylene?
A Well, first of all, the market, the application doesn't matter. It's the same toolbox; it's the same tool set. If I have a -- any widget made out of polypropylene that's underperforming, cracking, failing, what have you, it's the same toolbox. So it doesn't matter if it's a medical device, it doesn't matter if it's an automotive component; the same tools, the same approach, the same techniques are employed.
Q Have you analyzed polypropylene in any application that was cracking?
A I'm sure I have. I just can't recall a specific instance right now.
Q You can't -- you can't identify for the court any failure analysis that you performed on

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polypropylene material that was cracking?
MR. HUTCHINSON: Objection. Been asked and answered, Counsel.
THE WITNESS: I've done so many failure analysis on cracking parts that I just need probably some time to think about that. Maybe we can -- it will come to the forefront.
Q (By Mr. Thornburgh) Have you ever performed any degradation studies of failed, broken, cracked polypropylene material for any application?
A Yes. Absolutely.
Q Okay. And what application?
A The one that now comes to mind is I actually did a -- I looked at the fractography -- the fractography and the fracture behavior of a polypropylene accelerator pedal on a Toyota vehicle.
Q That's not a permanent implant, is it?
A No, but it's a device made out of polypropylene.
Q It's accelerated -- it's an -- it's a -- what did you say, a --
A Accelerator pedal.
Q Accelerator pedal?

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A Accelerator pedal.
Q Okay. So it's a pedal used in a Toyota vehicle that was cracked?
A That's correct.
Q And did you perform a chemical analysis to determine if the crack was the result of oxidation or degradation? Oxidation?
A No, but we certainly examined the fracture pattern, the fracture behavior, the origin of the crack, the type of material that it was.
Q Okay. But you didn't perform any chemical analysis of the cracked accelerator pedal, correct?
A Any chemical analysis, is that what you asked me?
MR. HUTCHINSON: He did.
MR. THORNBURGH: Looking for oxidation of the material.
THE WITNESS: We did not specifically look for oxidation of the material.
Q (By Mr. Thornburgh) Did you do FTIR analysis?
A We did.
Q To determine whether or not it was polypropylene?

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A Correct. We looked at the composition, we looked for contaminants, things of that nature.
Q You weren't looking for oxidation, though?
A Not specifically in that matter.
Q Have you ever performed a failure analysis of a polypropylene suture?
A I have not, but I have certainly -- let me just go back to that.
Q It's a yes or no question.
MR. HUTCHINSON: Hey, Steve, you're welcome to answer his question, so go on.
MR. THORNBURGH: There's not a question pending. He answered.
MR. HUTCHINSON: Yeah, there is. You can answer the question, Steve.
Q (By Mr. Thornburgh) You have not analyzed --
MR. HUTCHINSON: Hey, Dan --
Q (By Mr. Thornburgh) -- you have not performed --
MR. THORNBURGH: Hold on.
MR. HUTCHINSON: No, no.
MR. THORNBURGH: I want to make sure he understands my question.
MR. HUTCHINSON: No.

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Q (By Mr. Thornburgh) You have not performed --
MR. HUTCHINSON: You can answer the question, Steve.
Q -- a failure --
MR. THORNBURGH: Hold on a second.
MR. HUTCHINSON: No. Steve is trying to answer your question. Steve, go on and answer his question, and then Dan can follow up.
MR. THORNBURGH: I'm going to withdraw the question. I'm going to ask it a different way.
Q (By Mr. Thornburgh) Prior to this case, you have never performed a failure analysis of a polypropylene suture, correct?
A Prior to the case, I have not, but I have certainly analyzed all of the data around sutures that have taken -- been taken out of the body and analyzed through a number of different techniques.
Q As your role as a witness in this case, right?
A Correct.
Q Well, that wasn't my question. Before you

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were hired by Butler Snow, you've never performed a failure analysis of a suture device made out of polypropylene?
A Correct.
Q Prior to this case, have you -- you've never studied the biocompatibility of polypropylene mesh for the human tissue, correct?
A Correct, for this -- for that matter, correct.
Q You've never published on the subject of biocompatibility of polypropylene mesh in the human tissue, correct, sir?
A Correct.
Q Prior to being retained as an expert in this case, you've never spoken or presented on the topic of polypropylene mesh, correct?
A Correct.
Q You've never taught or lectured on the subject of polypropylene mesh, correct?
A I have not taught on mesh.
Q You have no understanding of the biomechanical properties of the pelvic floor, correct?
A Could you repeat that?
Q You're not an expert on the biomechanical

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properties of the pelvic floor, correct?
A Correct.
Q You're not a biologist?
A I am not a biologist.
Q You're not a molecular biologist?
A No.
Q What's -- do you know what I mean by "peer-reviewed publications"?
A I do.
Q What does "peer-reviewed publication" mean?
A Typically when a scientist writes a journal article, before it gets accepted by the -- by the authoritative body that governs that journal -- that journal itself, your study needs to be reviewed by peers and needs to be accepted by peers to make sure that you have followed the scientific method prior to publication.
Q You've never published any articles in a peer-reviewed journal concerning polypropylene mesh, correct?
A That is correct.
Q You've never published in peer-reviewed journals concerning any studies or testing that you -- that you conducted concerning polypropylene

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degradation, correct? And so for the record --
MR. HUTCHINSON: Dan --
Q -- for the record, you're --
MR. HUTCHINSON: Dan -- oh.
Q -- for the record, you're looking at Exhibit No. 2, your publication list, correct?
A That is correct. Specifically for polypropylene, no, but I have done some publications and presentations that look at oxidative degradation mechanisms for other thermoplastic polymers.
Q So the answer to my question is no, you have not published any of -- testing or work that you've performed analyzing degradation of polypropylene, correct?
MR. HUTCHINSON: Object to form.
THE WITNESS: Correct. However, it's the same toolbox that you use that we talked about earlier.
Q (By Mr. Thornburgh) Prior to this case, have you ever tested polypropylene for degradation?
A Oh, I'm sure I have, yes. As a matter of fact, another application comes to mind now that we're talking through this, yes.
Q What application?

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A I have looked at the degradation and loss in physical properties for a variety of different wheels that are used for lawn and garden equipment. They're made out of 30 percent glass-filled polypropylene.
Q Not isotactic, correct?
A No, it would be isotactic.
Q So 30 percent glass-filled polypropylene wheels used for garden equipment, right?
A Lawn and garden equipment, correct.
Q You've never tested polypropylene medical devices that have been explanted from the body looking for degradation, correct?
A I haven't tested it myself, but I've looked at a whole host of data.
Q In this case, right?
A In this case.
Q But prior to this case, you had never tested polypropylene for degradation of medical devices that were explanted from the human body?
A Correct. But, again, it's the same toolbox, whether it was explanted or not.
Q You've never published in the peer-reviewed literature on the subject of polypropylene, correct?
A No. But I would say that some of the

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literature actually pertains to what I'll call sister polymers.
Q That wasn't my question. My question was: You've never published in the peer-reviewed literature on the subject of polypropylene?
MR. HUTCHINSON: Objection. Been asked and answered.
MR. THORNBURGH: I didn't ask about sister polymers. I asked about polypropylene specifically.
THE WITNESS: Right, but polyethylene, polyphenylene ether, all of these polymers have very, very similar structures. And again, the approach, the tools, the analysis that gets done, there's not much differentiation between the two.
Q (By Mr. Thornburgh) Answer my question, okay? You have never published in the peer-reviewed literature on the subject of polypropylene specifically, correct?
A Polypropylene specifically, that's correct.
Q In fact, you've only tested one Prolene mesh device in your entire career, and that was for the purpose of serving as an expert witness in this case

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for the defendants or their lawyers, Butler Snow, correct?
MR. HUTCHINSON: Object to form.
THE WITNESS: Can you ask that one more time?
Q (By Mr. Thornburgh) You have only tested one Prolene mesh device in your entire career, and that was for the purpose of serving as an expert witness in this case for the defendants or for Butler Snow, correct?
A Correct, but I have reviewed scores of other test data that's relevant.
Q But that was for the purpose of this litigation, correct?
A Correct.
Q You've never tested a Prolene suture prior to this case, correct?
A Correct.
Q You've never tested any sutures prior to this case?
A Prior to this case, correct.
Q And you -- were you retained by Butler Snow or by Ethicon or Johnson & Johnson?
A Butler Snow.
Q Butler Snow, it's your understanding, is

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Johnson & Johnson and Ethicon's attorneys, correct?
A That's my understanding.
Q Have you ever provided any expert witness consultation or expert witness services for Butler Snow in the past? Let me ask a better question.
Have you ever worked -- or have you ever been retained as an expert or a consultant for Butler Snow?
A No, I don't believe so.
Q What law firms have retained you as an expert witness?
A I would have to go back and look. I don't --
Q Just name a couple.
A Bowman and Brooke would be one that comes to mind.
Q You have a list.
A I do.
Q You're looking at Exhibit -- you're looking at Appendix B to Exhibit No. 2, which is a list of your prior testimony; is that correct?
A Correct.
MR. HUTCHINSON: Dr. MacLean, take your time.
THE WITNESS: Latham Watkins would be another firm that has been hired -- I've been

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hired by. Lewis Thompson. Cremer Spina. Norton Fulbright Rose. Those are the ones that come to mind.

Q (By Mr. Thornburgh) All right. And you have -- in Appendix B of Exhibit No. 2, you have a list of testimony that you've given in the last couple years; is that correct?

A That's correct.

Q Have you given -- have you served as an expert witness in more than eight cases?

A I've served as a testifying expert in eight cases.

Q Have you served as an expert witness in cases where you haven't provided testimony?

A Yes, there have been other cases that I've been disclosed as expert -- as an expert that have either settled or are still pending.

Q Okay. And so let's go through this list, and then we'll talk about your work as an expert where you haven't offered or provided testimony.

A Okay.

Q So in your Appendix B, you have a list of cases, eight cases, where you've given testimony and you have -- there's some bold letters in each case

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name. Does that denote where -- which party you -- which party hired you to offer expert opinion testimony?

A That would be the retaining -- yes, the party that I was -- the beneficial party of that -- of that litigation through the -- through the retainer from the law firm, correct.

Q Okay. So Workhorse Custom Chassis, LLC versus Robert Bosch, LLC, was that a lawsuit that was brought by and against two corporations?

A Correct.

Q And what was the -- what type of expert opinion testimony did you provide?

A I can tell you that that matter involved phenolic pistons used in brake systems for RV vehicles, and the allegation was that the pistons were swelling in the field over time and causing the brakes to underperform in the field.

Q So that was an automotive application?

A Recreation -- yes, RV, automotive, correct.

Q And then Trice, et al. versus Toyota Motor Corporation, you were retained by Toyota Motor Corporation or their attorneys?

A Correct.

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Q And so you were retained by the defendant in that case?

A Correct.

Q And what did that case involve?

A That case involved a stuck -- excuse me -- stuck throttle allegation.

Q Another automotive application?

A Yes. There are polymer components throughout the throttle body system, the throttle control system, I should say, and the behavior of those components under end-use conditions was called -- was being called into question.

Q Alberto, et al. versus Toyota Motor Corporation, again, you were retained by Toyota Motor Corporation, a corporate defendant, regarding another -- is that another stick throttle issue?

A That was an unintended acceleration. Those matters were a bit different, but it was an unintended acceleration matter. That was actually the one we talked about earlier with the polypropylene fractured accelerator pedal.

Q And you were retained by the defendant in that case?

A I was. I was retained by their law firm,

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correct.

Q The law firm who was retained by the defendant corporation?

A That is correct.

Q Metropolitan Property & Casualty Insurance versus LG Electronics, you were retained by LG Electronics or their lawyers, correct?

A That's correct.

Q And again, you were an expert witness on the defense side of the V, correct?

A Correct.

Q And what did that litigation involve?

A That litigation involved low-density polyethylene tubing that connects the water supply system from your home to the ice maker and water supply system in refrigerators.

Q And you were -- the next one is Nease versus Ford Motor Company. Again, you were retained by the defendant or the defendant's lawyers in that litigation, correct?

A That's correct.

Q And that was another automotive application, a case involving some incident regarding -- some failure of a Ford Motor Company vehicle, correct?

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A Some alleged performance issues related to a Ford vehicle, correct.
Q And was Nease an injured plaintiff?
A Correct.
Q And let me go back a little bit. Was Trice an injured plaintiff?
A Trice was an injured plaintiff, correct.
Q And you represented the corporate defendant, right?
A Through their attorney, correct.
Q Alberto, was that an injured plaintiff?
A Correct.
Q And you represented Toyota Motor Corporation or their attorney, right?
A Yes.
Q Nease was another injured plaintiff and you represented the defendant corporation?
A Correct.
Q Wubker, et al. versus A&A Manufacturing Company, what was -- what was that case about?
A That case was about a dock leveler device, an airbag for the dock leveler. D-O-C-K, L-E-V-E-R -- sorry. L-E-V-E-L-E-R.
Q What was the allegation in that case?

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A That the airbag ruptured during use and injured the maintenance person that was maintaining it at the time.
Q And Wubker was an injured plaintiff?
A Correct.
Q And you represented, on behalf of the lawyers, A&A Manufacturing Company, a corporate defendant, correct?
A That is correct.
Q Promethean Insulation Technology, LLC versus Reflectix Incorporated, you represented the defendant corporation in that case as well, correct?
A Correct.
Q And what did that lawsuit entail --
A Those are two --
Q -- or involve?
A Those are two companies that are in litigation right now regard -- revolve -- excuse me -- regarding an intellectual property matter.
Q And you represented a corporate defendant in that case?
A Yes, who was being sued by a corporation.
Q And Nettleton, et al. versus Ford Motor Company, you again represented the Ford Motor Company,

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a corporate defendant, correct?
A Correct.
Q Against an injured plaintiff?
A No, no injured plaintiffs in that matter. It's a class.
Q A class of consumers who sued Ford Motor Company because of some defect or alleged defect in a product that Ford Motor Company sold?
A Correct, but no injured parties.
Q But you represented the corporate defendant, right?
A Correct.
Q Okay. Have you ever represented an injured plaintiff?
A I have not.
Q Other than these eight cases where you've testified as an expert witness, how many other cases have you been retained as an expert witness or consultant?
A Probably on the order of 5 to 10 additional matters.
Q So approximately 20 cases?
A Sounds about right.
Q All on behalf of a corporate -- well, for the

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vast majority of those, those were -- you were retained by either a corporate defendant or their lawyers, correct?
A Not in all cases, no. There are some matters that are -- I'm not being -- excuse me -- I'm not representing the defense in some matters.
Q So in those matters where you're not representing -- or haven't been retained as a witness or consultant in those matters, you were retained by a corporate plaintiff?
A Correct, or a -- yeah, or a complaint -- yes, correct.
Q You've always -- a hundred percent of the time that you've offered your expert services has been on behalf of a corporation?
A Yes.
Q And as we saw in the newsletter that we looked at earlier, you were hired by -- Exhibit No. 7, you were hired by Exponent to continue to offer litigation services, correct?
MR. HUTCHINSON: Object to form. Mischaracterizing the document. Counsel, also it says clearly he was hired for other things. It's a misrepresentation of the

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document.
MR. THORNBURGH: That's what the document says.
THE WITNESS: And litigation failure -- nonlitigation failure analysis.
Q (By Mr. Thornburgh) On behalf of corporate clients?
A It doesn't say that.
Q Well, that's what you do, right?
MR. HUTCHINSON: Object to form. Argumentative.
Q (By Mr. Thornburgh) You represent -- you get retained -- or Exponent gets retained and you provide services for corporate clients --
MR. HUTCHINSON: Object --
Q -- a hundred percent of the time?
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) Right?
MR. HUTCHINSON: Don't answer that. He's already answered that question, Counsel.
MR. THORNBURGH: No, he hasn't.
MR. HUTCHINSON: Yeah, he has.
THE WITNESS: First of all, if you're

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asking about Exponent, the answer is no. If you're asking about me, I've already given the answer.
Q (By Mr. Thornburgh) You -- as an employee of Exponent, you have been retained or offered services a hundred percent of the time for corporate clients, correct?
MR. HUTCHINSON: Object to the form. Been asked and answered.
THE WITNESS: Same answer.
Q (By Mr. Thornburgh) Yes or no?
A I answered yes already. Go back and look.
Q Okay. The answer is yes, right?
A Still yes.
MR. THORNBURGH: Use the restroom.
MR. HUTCHINSON: Okay.
MR. THORNBURGH: Break.
THE VIDEOGRAPHER: We are now going off the video record. The time is currently 10:53. This is the end of Tape No. 1.
(Recess taken.)
THE VIDEOGRAPHER: We are now back on the video record with Tape No. 2. The time is currently 11:08 a.m.

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Q (By Mr. Thornburgh) Doctor, there are other Exponent employees who have also been retained by Ethicon and Johnson & Johnson in this litigation, correct?
A I believe so.
Q Dr. Kevin Ong?
A I -- yes, I believe he's been retained. I don't know if it's specific to this matter.
Q And you're aware that Marta Villarraga and Dr. Reitman are both Exponent employees who have been retained by Johnson & Johnson, Ethicon, and/or other mesh manufacturers?
MR. HUTCHINSON: Object to form.
THE WITNESS: I'm not aware of their involvement with Ethicon or Johnson & Johnson.
Q (By Mr. Thornburgh) Do you know Dr. Villarraga and Dr. Reitman?
A I do.
Q You are aware that they've been -- they've been retained by defendants in the mesh litigation, correct?
A Correct.
Q Did you communicate with them concerning this

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case?
A No.
Q Have you talked to any experts in this litigation?
A Yes.
Q Who have you talked to?
A I've talked to Dr. Shelby Thames.
Q Any others?
A No.
Q And Dr. Shelby Thames is a polymer scientist?
A He is.
Q And he's serving as an expert polymer scientist in this case, correct?
A I'm not sure. I believe he is.
Q What did you talk to Shelby -- Dr. Shelby Thames about?
A Polymer science.
Q What about this case specifically?
A We talked about a couple of different routes to get carbonyl functionality inside the IR spectra.
Q A couple different roads to get carbon --
A Routes, a couple of different routes.
Q -- carbonyl functionality inside the IR spectra?

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A Yes.
Q What do you mean by that?
A Well, I'm sure we'll get into it at some point, but carbonyl functionality has been seen in several IR spectra from explants or exemplar units. And him and I were discussing the various ways that that carbonyl functionality could show up.
Q So you agree that there have been carbonyl -- and by carbonyl, we're talking about groups, right, CO bonds?
A Certain functional groups, correct, CO bonds.
Q Which would be an -- which could be an indication of oxidation or degradation through the oxidative pathway?
A There are a number of different molecules that can have carbonyl functionality in them.
Q One of those would be oxidation, correct?
A Oxidation could cause carbonyl functionality to develop in certain polymers, correct.
Q Including polypropylene, right?
A Yes, correct.
Q You understand that Kevin Ong has been retained in this case, right?
MR. HUTCHINSON: Object to form.

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THE WITNESS: I --
MR. HUTCHINSON: Counsel, just for the record, Dr. Ong has not been designated as an expert in this case.
MR. THORNBURGH: He hasn't?
MR. HUTCHINSON: No.
MR. THORNBURGH: Okay.
THE WITNESS: That's -- that was why --
MR. THORNBURGH: I thought he had.
MR. HUTCHINSON: Wait just a minute. No, in all fairness, he hasn't.
MR. THORNBURGH: Okay.
MR. HUTCHINSON: Not in the Mullins consolidated case.
MR. THORNBURGH: Okay.
Q (By Mr. Thornburgh) What do you understand -- well, let me ask you this question: You haven't analyzed any of the mesh TVT devices that were explanted from any of the plaintiffs in this case, correct?
A That's correct.
Q And Dr. Thames did that, correct?
A I --
MR. HUTCHINSON: Object to form.

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THE WITNESS: I am not aware of what Dr. Thames did in this matter.
Q (By Mr. Thornburgh) Did anybody -- are you aware of anybody that analyzed explanted TVT devices from any of the plaintiffs in this case?
MR. HUTCHINSON: Are you talking about the 37 plaintiffs?
MR. THORNBURGH: Thirty-seven plaintiffs.
THE WITNESS: I am not aware of anybody that's done any work on explants from these 37 plaintiffs.
Q (By Mr. Thornburgh) Are you aware that there were -- there are and have been TVT explants available from plaintiffs in this case?
MR. HUTCHINSON: Object to form. Counsel, are you talking about the 37 plaintiffs?
MR. THORNBURGH: I'm talking about the 37 plaintiffs.
MR. HUTCHINSON: Okay.
THE WITNESS: I don't recall if I was made aware of that or not.
Q (By Mr. Thornburgh) Ethicon never came to

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you and asked you, their polymer scientist, to analyze any explanted meshes for any of the women who have explant mesh specimens available, correct?
A They did not.
Q Sitting here right now, you have no idea how many TVT explant specimens are available from this group of 37 plaintiffs, right?
A Can you ask that again?
Q Sitting here right now, you have no idea how many TVT explant specimens are available from this group of 37 plaintiffs, right?
A No, I don't, not without looking at some documents, I wouldn't be able to.
Q Did you ever ask Ethicon or Ethicon's attorneys whether any of the 37 plaintiffs had mesh explanted from their bodies?
A I did.
Q And what did they tell you?
A Yes. The answer is yes.
Q And did you say, "It might be a good idea to analyze some of those TVT specimens to determine if there's evidence of oxidation"?
A I made -- I made that request. I did not receive any mesh.

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Q So you made a request to analyze explanted TVT specimens to Ethicon's attorneys, and they did not provide to you any of the explanted specimens from this group of 37 plaintiffs, correct?
MR. HUTCHINSON: Object to form. And, Counsel, if you could give us some details on when these 37 explants were available, I'd like to know that.
MR. THORNBURGH: Well --
MR. HUTCHINSON: Could you do that?
MR. THORNBURGH: -- it's not my deposition.
MR. HUTCHINSON: Right.
MR. THORNBURGH: But you know there's a pathology protocol that we've been following.
MR. HUTCHINSON: Correct.
MR. THORNBURGH: So --
MR. HUTCHINSON: And if you could give us some information about when these 37 explants were available for us to inspect, I would really like to hear that.
MR. THORNBURGH: It's already been done, but it's not my deposition.

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MR. HUTCHINSON: Okay.
MR. THORNBURGH: I don't answer questions under oath right now. That's his job. My job is to ask the questions.
MR. HUTCHINSON: So you're not going to give us any information about when these 37 explants were available?
MR. THORNBURGH: You already have -- you already have the information regarding --
MR. HUTCHINSON: When was it?
MR. THORNBURGH: -- the availability of -- I've talked to Andy Snowden about it.
Q (By Mr. Thornburgh) Andy Snowden went up to Toronto and participate -- are you aware that Ethicon's lawyers went up to -- with Kevin -- with Dr. Ong, went up to Toronto and divided some mesh specimens from this group of TVT plaintiffs?
A I don't -- I don't recall. I don't remember if that was made -- if I was aware of that. I just don't know.
Q You were never made aware that Ethicon was provided with half of some of the available specimens from this group of TVT plaintiffs?
MR. HUTCHINSON: Object to form.

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Q (By Mr. Thornburgh) Right?
A I don't recall if I was made aware of that.
Q And you actually asked Ethicon's lawyers if you could analyze some explanted mesh from this group of TVT plaintiffs, correct?
MR. HUTCHINSON: Same objections. It's been asked and answered, Counsel.
THE WITNESS: Yeah, same answer.
Q (By Mr. Thornburgh) The answer is yes, right?
A Correct.
Q And they never provided it to you?
A I did not receive any mesh.
Q So you're offering opinions in this case without having had the opportunity to actually do your own analysis of explanted TVT mesh specimens that were made available to the defense, correct?
MR. HUTCHINSON: Object to form.
THE WITNESS: Correct. But my scope of work is a little bit different in this matter. And I have certainly analyzed all of the existing data that's available for the last three decades on these exact TVT devices or sutures or sister products. And I was

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testing some hypotheses of Dr. Iakovlev's work that he didn't do in his work.
Q (By Mr. Thornburgh) You said your scope is a little bit different. Who determined your scope in this case?
A I think it was discussed between me and the -- and counsel.
Q And your scope didn't include actually analyzing TVT specimens that were explanted from this group -- from some of the women in this group of cases?
A I --
MR. HUTCHINSON: Same objection.
THE WITNESS: I was ultimately asked to look at all of the historical information that was available, including all the polymer science, all the general science, all the testing, all the approaches, all the results that have been generated, and form my own opinions as to what is happening with this mesh in vivo.
Q (By Mr. Thornburgh) Do you know if anybody analyzed mesh specimen from this group of plaintiffs?
A What do you mean? Who?
Q Do you know if any other expert that has been

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retained by Butler Snow has analyzed any of the mesh explant TVT devices that have been removed from some of these plaintiffs?
A I do not know.
Q Turning back to Exhibit No. 2, there's a "Limitations" section. And just so the record is straight, you've never looked at any mesh device in this litigation that has been explanted from a woman's pelvis, right?
A That's been asked and answered.
Q But in this -- you haven't in any -- in any TVT case?
A For these 37?
Q In any case, ever.
A Correct.
Q If you turn to page 6, the limitations, it says -- of Exhibit 2, it says, "At the request of Butler Snow LLP, Exponent reviewed relevant scientific literature, historic documented studies and expert reports for the pending litigation."
It doesn't say you did this. It says Exponent reviewed. Who at Exponent reviewed relevant scientific literature, historic documented studies and expert reports in this litigation?

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A First of all, I did. But the additional "we" would be a few of my colleagues in the polymer science practice.
Q Okay, so tell me who those folks are.
A Dr. Benight. Dr. Moll.
Q Dr. -- how do you spell Dr. Moll's name?
A M-O-L-L. Dr. Garcia. And Dr. McGann, M-c-G-A-N-N.
Q M-c-G-A-N-N?
A Correct.
Q So Dr. Benight, Dr. -- make sure I understand your testimony. Dr. Benight, Dr. Moll, Dr. Garcia, and Dr. McGann helped you review the scientific literature, historic documented studies and expert reports in this litigation?
A Correct. And we do that because it's important as scientists to basically do an internal peer-review process. I read something, you would read something, we'll debate the approach, the science, the results, and come to some understanding on where we agree, where we may disagree, and that's how our scientific process works. So it's important that not just me, but other colleagues with similar backgrounds, similar levels of expertise, read the literature as

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well, and then we discuss it.
Q So you relied on your other four experts or other four employees at Exponent to provide you with, what, summaries of what they read?
A Not -- in some cases, summaries, but in most cases I would say, "Dr. Moll, please read this piece of literature or these pieces of literature, and tomorrow we're going to discuss them for a few hours," or, "Dr. McGann, please go off and do some research on this particular mode of degradation for polypropylene. I will do the same. We'll come back and discuss it." That might work its way into the report, things like that.
Q So when you would receive summaries from some of these other employees at Exponent, would they provide those summaries to you in writing?
A No. Typically orally.
Q So you did not review all of the documents, literature, depositions, and other materials that are identified on -- in Appendix C of your expert report, correct?
A I can't tell you that I have read every single page of every single document, but I can assure you that I have read literally thousands of pages of

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information on this matter.
Q And you -- in addition to -- well, there's two parts of Exhibit [sic] No. C. There's a list of documents reviewed, and then there's a second list called "Steven MacLean, Reliance List in Addition to Materials Referenced in Report."
A Correct.
Q And so, again, you didn't review all of this material either, correct?
A A lot of that is duplicative. That was Butler Snow bolting on to our report the -- all of the information that they knew they sent us. And so my -- my list and my report would have those documents, plus anything that we went out to the public domain, to the public literature, and acquired and reviewed on our own.
Q Okay. And so at least for the internal Ethicon documents, those were handpicked by Ethicon's attorneys and provided to you, correct?
A I don't know if I'd use the term "handpicked." They were furnished to us from Butler Snow.
Q Well, you didn't go out and review their database of documents on your own, correct?

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A No. But I'm sure there are occasions where I said, "Hey, does XYZ document exist," or something like this, and they may have gone off and looked and sent it to me.
Q And so you relied on Ethicon to provide you with documents that Ethicon's lawyers believed was relevant for the scope of your opinions in this case?
A Yeah, with the two-way communication that I just described.
Q Can you tell me which documents or materials on -- in Appendix C and the addition -- additional materials that Butler Snow provided were reviewed by you?
A Oh, I couldn't -- I couldn't do that. That would take way too much time.
Q Do you know which materials were reviewed by Dr. Benight, Dr. Moll --
A Not specifically.
Q -- Dr. Garcia?
A No, not specifically.
Q So you have no idea what they reviewed?
A I have a general sense of what they reviewed. I couldn't cite you the specific documents top to bottom.

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Q And there's no written memorandum that would identify what these other doctors at Exponent reviewed and shared with you later on, correct?
A Correct.
Q And so you relied at least in part on the conclusions and opinions reached by these other doctors at Exponent, correct?
A No. No. The opinions that I've formed are all mine.
Q You relied on their conclusions, right?
A No, I didn't rely on their conclusions. I had scientific discussions with them to help crystallize my opinions.
Q No pun intended, right?
A None.
Q But you can't tell me which documents or materials were even reviewed by these other folks at Exponent?
A Not with specificity, I can't.
Q Who is Dr. McBright [sic]? What's her first name?
A Doctor who?
Q Dr. Benight. What's her first name?
A Stephanie.

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Q What's her background?
A She has a chemistry background, but she also has a polymers background as well.
Q She's mostly a chemist?
A She has a strong chemistry background, correct.
Q What about Dr. Moll?
A Dr. Moll, she is a polymer science -- polymer science and engineer -- polymer scientist and engineer. She is directly on my staff.
Q How about Dr. Garcia?
A Dr. Garcia belongs to our biomedical/biomaterials practice. That's her expertise.
Q You're not a biomedical --
A I am not.
Q -- scientist, correct?
A Correct.
Q And you're not a part of the biomaterials practice; is that correct?
A I am not. She is.
Q And you're not offering opinions in this case concerning the biomedical -- you're not offering biomedical opinions in this -- in this case, correct?

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A I am not. I'm here to talk about polymers.
Q Who is the fourth person? Somehow I lost my list.
A Dr. John McGann.
Q I'm sorry, what was Dr. Garcia's first name?
A Mariana. M-A-R-I-A-N-A.
Q And Dr. Moll's first name?
A Jericho. J-E-R-I-C-H-O.
Q And Dr. John McGann, what is his background?
A Similar to Stephanie's; chemistry, polymer science. He's also part of our polymer science practice.
Q You're not a chemist, right?
A I'm not a chemist. I've taken a number of different chemistry classes.
Q You don't hold yourself out as an expert in chemistry, correct?
A As an expert in chemistry? Not an expert in chemistry, but I'm certainly very knowledgeable about chemistry, organic chemistry, things of that nature.
Q Did Stephanie Benight -- Dr. Benight, Dr. Moll, Dr. Garcia, and Dr. McGann help you write your expert report?
A They provided some draft inputs to me.

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Q What section did Dr. Benight write or draft?
A I don't recall specifically which section at this point. The final body of work is mine.
Q Well, she's a chemist.
A Uh-huh.
Q Did she provide some chemistry analysis in your expert report?
A I don't -- I don't specifically recall. I'm sure we had some chemistry discussions along the way.
Q What sections did Dr. Jericho Moll write or help draft?
A Jericho and I worked on the seven-year dog study section. I recall that. We worked together quite a bit on the Prolene section.
Q By "Prolene section," do you mean the Prolene microcrack section?
A I mean the section that starts on page 19 that's labeled "Prolene."
Q Okay. What section did Dr. Garcia help you write?
A I'd say Dr. Garcia mostly contributed to portions of the second report, which I'll call the microscopy report.
Q And is that because Dr. Garcia was the person

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who conducted those studies?
A Dr. Benight conducted those studies with input from Dr. Garcia.
Q And what section did Dr. McGann help you write?
A I believe I asked him to critique just some of the public literature, but I did a lot of that as well. So I think that was the extent of his work.
Q So in order for me to understand sort of who wrote which sections of the report, I'd have to look at a draft of your report?
A There's one and only one draft of this report. It's a living document. And what typically happens is, like I said, we would have a discussion, one of us might write up a paragraph or two. I have final editorial privileges of the document. I might massage it and make it my own, add my own paragraph, sections, things like that.
Q Let me make sure I understand sort of their roles a little bit more.
A Sure.
Q So Dr. Stephanie Garcia [sic] would have, with the help of Dr. --
A Benight.

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Q -- Benight, would have worked on the testing that was done in your second report and the drafting of your second report; is that correct?
A Correct. In part, correct.
Q And did any other employees of Exponent help with that regard?
A On the second report?
Q Yes.
A No, I do not believe so.
Q All right. And then Dr. Moll and you --
A Let me just rephrase that. We have an internal quality control process, so there may have been other folks beyond -- once the final draft is ready, there may have been other peer-reviewers that had provided comments or editorial changes to the document.
Q Who are those folks?
A They would be listed on the bill.
Q Are they Ph.D.s? Are they doctors?
A Typically, yes. But it's nothing more than getting a fresh set of scientific eyes on a written body of work to make sure that there's nothing that's not consistent with the scientific method or to catch potential typos and editorial issues.

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Q And then Dr. Jericho Moll would have worked on the seven-year dog study --
A Uh-huh.
Q -- section of your report?
A Correct.
Q And Dr. Garcia would have worked on the second report, and then John McGann would have worked on what section?
A Some -- I had him, I believe, critique some of the --
Q Critique some of the peer-reviewed publications?
A That's right. Review, synthesize, and critique.
Q So he would have worked on the section that begins where, or sections that begin where?
A Twenty-four, page 24.
Q Twenty-four through what page?
A Thirty-two.
Q And that would have been the publications concerning degradation of polypropylene, including Prolene?
A Correct.
Q Any other sections?

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A Not that I recall.
Q In the "Limitations" section on page 6 of Exhibit 2, you go on to say, "Exponent investigated specific issues relevant to this report as requested by the client."
What specific issues did Ethicon investigate at the request of Butler Snow, Ethicon's attorneys?
MR. HUTCHINSON: Object to form.
THE WITNESS: It's the same answer I gave you earlier. They asked me to review a series of historical documents and data, current expert reports, older expert reports, synthesize it, and draw my own independent conclusions on the results.
Q (By Mr. Thornburgh) The paragraph goes on to say, "The scope of services performed during this investigation may not adequately address the needs of other users of this report, and any reuse of this report or its findings, conclusions, or recommendations is at the sole risk of the user."
So the scope of the services performed may not adequately address the needs of other folks who may read your report and want to know a little bit of information about polypropylene degradation,

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specifically degradation as it relates to the TVT device?
MR. HUTCHINSON: Object to form.
THE WITNESS: Yeah, I don't think I understand your question.
Q (By Mr. Thornburgh) Well, I don't understand the sentence. So maybe you can help me understand it. It says the scope of services that you and your other colleagues performed may not adequately address the needs of other users.
A Correct, so --
Q What do you mean by that?
A Well, the scope of the work was basically what I've already described to you, and that's exactly what Ethicon asked us to do, asked me to do, and that's the work that we did. I'm not -- I guess I'm not sure what trouble you're having understanding that.
Q That it may not adequately address the needs of other users.
A It may not. Another user might pick up this report and not understand it because they don't have any polymer science background, may -- and as a result, may draw erroneous conclusions from it. So all I know is that Ethicon asked me to do the work that I've

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already outlined for you, and we've generated a report that summarizes that report and that addresses the specific scope of work that they asked us to do.
Q You go on in the next paragraph to say, "The findings presented herein are made to a reasonable degree of engineering certainty." Did I read that correctly?
A You did.
Q So the scientific specialty employed by you in writing this report and reaching your opinions were of those of an engineer; is that correct?
A Not solely as an engineer.
Q An engineer and a --
A Scientist.
Q Polymer scientist?
A Correct.
Q You're not offering any other opinions outside the scope of engineering and polymer scientist -- science; is that correct?
A And general materials science.
Q What opinions are you offering as a general materials scientist?
A There are materials, such as proteins, that actually are polymers, but for the sake of this

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discussion we'll call them proteins, that are present in and around the filaments and fibers of the mesh that other scientists have characterized. And I'm relying on some of that data that I've seen. So that is why I would include proteins. The formaldehyde solution, formalin fixation solution.
Q You've never conducted any of your own studies concerning the formaldehyde proteined -- protein polymer, correct, the theory of -- you're never conducted your own testing or studies concerning the theory that the cracked outer layer of the polypropylene Prolene TVT mesh fibers is a formaldehyde-protein polymer, correct?
A I don't have to. That science is already founded.
Q That's not my question. My question is: You've never conducted any studies --
A No, but --
Q -- in that regard?
A -- several --
MR. HUTCHINSON: Hey, one at a time. Dr. MacLean, you can finish answering the question, please.
THE WITNESS: The science is well

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established, and other folks have confirmed it. I've seen it in the data. It exists.
Q (By Mr. Thornburgh) You've never conducted your own studies, correct?
A It would just be -- it would be redundant. Correct.
Q You've never looked at explanted polypropylene materials, period, right?
A Well, I've looked at plenty. I've looked at plenty of micrographs. I've looked at plenty of photographs --
Q In this --
MR. HUTCHINSON: Hold on. Dan, stop. Dr. MacLean, you can finish answering the question.
MR. THORNBURGH: In this litigation.
MR. HUTCHINSON: Hey, excuse me, Dan. Dr. MacLean, you can finish answering his question.
THE WITNESS: I have looked at more micrographs, photographs, pictures, images of so-called cracked mesh than I can count for this litigation --
MR. THORNBURGH: After --

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THE WITNESS: -- for this matter.
Q (By Mr. Thornburgh) Your question [sic] and testimony a moment ago was, "There are materials, such as protein, that actually are polymers, but for the sake of this discussion we'll call them proteins, that are present in and around the filaments and fibers of the mesh that other scientists have characterized. And I'm relying on some of that data that I've seen."
What data are you relying on that you suggest you've seen in this statement?
A Visual observations that people have done, the IR data that's out there that show clear evidence of protein. And just reading, I've read some literature about foreign body response and things of that nature. So just knowing that proteins actually get to the site and form. So it's really a culmination of all those things, looking at the public literature, looking at the historical documentation that's been generated either by Ethicon or by opposing experts. It's well established that proteins are present.
Q You say the visual observations and IR data that other people have reported. Are you referring to Dr. Thames?
A I'm referring to IR data from Ethicon

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throughout all of their studies. I'm referring to data I believe I've seen from Dr. Jordi. And there could be others.
Q Is Dr. Thames one of those individuals?
A I just don't recall.
Q Have you read Dr. Thames's expert reports?
A From the Bellew matter, I have.
Q And you share a lot, if not all, of the opinions that Dr. Thames has expressed in those reports or in his depositions, correct?
A I wouldn't make that characterization. I have my own opinions.
Q You share the same opinion?
A No, not necessarily. I have my own opinions. I'll make -- I'll let someone else make that distinction.
Q And you say you're also relying on the public literature, which has shown visual observation and discussed IR data. What publications are you referring to?
A A lot of the publications that are in my expert report. Clave mentions biologic materials. I'm sure Costello does. I'm sure there are others. We actually see biological material on -- in Wood's work,

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we see biologic material. You can physically see it.
Q That's what your -- that's what your report says?
A That's what my report says and that's what that journal article shows.
Q And you can see it how?
A You can see it in some of the macro-photography in her -- in the report, in the journal article.
Q So you think that the macro-photography of the explanted polypropylene material analyzed by Dr. Woods shows protein?
A Biological material that's most likely protein or proteinaceous in nature.
Q Is that the section that was written by Dr. McGann?
A Let me make it clear. The entire written report is my body of work. I got draft inputs from the people that I've already mentioned to you.
Q That's a section that was drafted by Dr. McGann, right?
A Portions of it were. The ultimate text that's in here is mine.
Q And so it's your opinion that the Wood

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article, scanning electron microscopy shows biologic material? Is that your opinion? Is that what you're saying?
A Can you just let me reference something so I can answer you more specifically. You're asking me about a very specific micrograph. I'm trying to find it.
Q By "micrograph," you're talking about scanning electron microscopy, right?
A No, you are.
MR. HUTCHINSON: Dan, hold on just a minute. The doctor is trying to answer your question. If you'll give him just a minute, okay?
THE WITNESS: It's always the last one. This is what I'm referring to. Figure 1 of the Wood report.
Q (By Mr. Thornburgh) Figure 1 of the Wood report. Which number?
A Figure 1D, E, and F, those are all photomicrographs of meshes, not necessarily Prolene-based meshes, that were explanted and cleaned, which is the most important thing. You can still physically see biological material in and around the

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mesh.
Q Well, let's look at A, okay. A is the cleaned -- the cleaned mesh?
A It's not cleaned. That's an exemplar. It's not cleaned.
Q Are you telling the ladies and -- let's go ahead and circle on Exhibit -- on Figure 1 -- sorry, hold on one second.
Are you -- have you read Dr. Thames' prior depositions?
A I believe I may have read portions of his Bellew deposition.
Q Did you talk to Dr. Thames about the Wood article?
A It may have come up.
Q And are you aware that Dr. Thames has testified in prior depositions and in other cases that the Wood article actually showed degraded polypropylene?
A Yeah, that -- I believe that's his belief, correct.
Q And so you disagree with Dr. Thames?
A I would say it's not conclusive enough and there's evidence to show that there are other molecules

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in play.
Q So my question was: You disagree with Dr. Thames's opinions, an opinion that he's expressed in this litigation that the Wood article in Figure 2D shows degraded polypropylene?
MR. HUTCHINSON: Object to form. Mischaracterizes --
Q (By Mr. Thornburgh) Do you disagree with that --
MR. HUTCHINSON: Wait. I'm sorry. Object to the form. It mischaracterizes the evidence. And, Counsel, just for the record, Dr. Thames has not been deposed in this litigation.
MR. THORNBURGH: He's been deposed in -- he's been deposed in the mesh litigation about the Wood article, and Dr. Thames said and testified that it was his opinion that the Wood article demonstrated degraded mesh that degraded through the oxidative pathway.
THE WITNESS: That's --
MR. HUTCHINSON: Hold on just a minute.
MR. THORNBURGH: And --

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MR. HUTCHINSON: Wait a minute. Finish your question, Dan. Are you -- are you finished with your question?
Q (By Mr. Thornburgh) Do you understand that he's testified to that in prior cases?
MR. HUTCHINSON: Okay, hold on just a minute. Object to form. Also mischaracterizes testimony.
Dan, if you have a copy of Dr. Thames' transcript, we'd like to see it. Do you have a copy?
Q (By Mr. Thornburgh) Do you -- do you understand that's his opinion, yes or no?
MR. HUTCHINSON: Dan, do you have a copy of Dr. Thames' transcript?
MR. THORNBURGH: I do.
MR. HUTCHINSON: Okay. Can we see it, please?
MR. THORNBURGH: Well, I'm not going to look for it right now, but we'll look at it later on.
THE WITNESS: What's your question?
Q (By Mr. Thornburgh) Let's assume that Dr. Thames testified that the Wood article, the

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polypropylene material explanted in the Wood article and analyzed, showed evidence of oxidatively degraded polypropylene. Would you disagree with that opinion?

MR. HUTCHINSON: Same objections.

THE WITNESS: This is how I will answer it. There's a carbonyl peak present that he looks at and believes it's an indication of polypropylene oxidation. However, there are other peaks when I look at the PTFE mesh, when I look at the PET mesh, and I look at their IR spectra, there are other accounted-for peaks that might suggest something other than oxidation is going on.

Q (By Mr. Thornburgh) I'm talking about the polypropylene.

A I understand what you're --

Q I'm not talking about --

A -- talking about.

Q -- PET or -- PET or PTFE.

A I understand what you're talking about. I'm telling you that if you look at the data in its totality and you look at some of the other peaks that have actually worked their way into the other materials -- and by the way, those peaks gets masked in

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the polypropylene material because they already have functional groups at 2800, 2900. So if you look at all that data in its totality, you could make the argument that, yes, it might be oxidation, but it also could be some sort of plasticizer, natural plasticizer in the body, that has a carbonyl-containing functional group.

Q So let me just understand your opinion here.

A Sure.

Q If Dr. Thames has testified that this was degraded, oxidatively degraded polypropylene, you would disagree with his opinion?

MR. HUTCHINSON: Object to form. Asked and answered, Counsel. He just explained to you his opinion about that.

THE WITNESS: It's not a yes or no answer. I don't disagree with him. I'm saying that there could be another reason why that carbonyl peak has shown up in that range.

Q (By Mr. Thornburgh) Okay. So then let me -- entertain me for a moment.

A Sure.

Q In the Wood article, you would agree that the polypropylene material analyzed could be oxidative

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degradation, right?

A I'm saying that the carbonyl functionality, it's just that, it's carbonyl functionality. That is a ubiquitous molecule in organic molecules -- sorry, it's a ubiquitous functional group within organic molecules. And you can't look at the carbonyl peak at 1740, 1720, wherever it is, and just say it's oxidation. It's not definitive enough.

When you look at the in vivo environments coupled with -- and we're not even talking about Prolene, by the way, in this -- that needs to be on the record. There's nothing that suggests or even confirms that Prolene was part of the Wood study. So let's get that on the table. But just in general, if you look at the material composition of Prolene and if you look at the in vivo environments of this -- of this mesh, there are way too many molecules present that have carbonyl functionality to simply go ahead and look at that peak and assign it to oxidation. You just can't do that. It's scientifically unsound.

Q Well, why don't you look at the Wood article -- just so the record is clear, the Wood article was published in 2013, right? Why don't we just go ahead and mark it as Exhibit No. 8 since we're

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talking about it. We kind of jumped to it, but might as well talk about it and mark it.

MR. HUTCHINSON: You got a copy?

(Exhibit 8 marked for identification.)

Q (By Mr. Thornburgh) Okay. And you understand that the -- Wood and her colleagues analyzed explanted polypropylene, PTFE, and PET hernia meshes from individual plaintiffs -- patients, right?

A I do. Well, no, it's -- I believe it's one patient.

Q From an individual patient?

A Correct.

Q Okay. And if you turn to the -- if you look at the abstract, first of all, it says, "Synthetic mesh materials are exposed to foreign body responses, which can alter physicochemical properties of the material." Did I read that accurately?

A You did.

Q And then it goes on and says that three mesh materials, including a polypropylene mesh, was analyzed from a single patient, and the results from infrared spectroscopy demonstrated significant oxidation of the polypropylene mesh, while ePTFE and PET showed slight chemical changes that may be caused by adherent scar

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tissue. Differential scanning calorimetry results showed a significant decrease in the heat of enthalpy -- enthalpy -- did I pronounce that correctly --

A You did.

Q -- and melt temperature in the polypropylene mesh.

Okay, so just from looking at the abstract, we're going to dig in a little bit deeper --

A Uh-huh.

Q -- but the scientist here performed a number of different testing to determine whether or not there was evidence of oxidative degradation of the polypropylene material and the other mesh materials as well, right?

A Correct.

Q One of those was scanning electron microscopy, right?

A Correct, which tells you nothing about oxidation.

Q That wasn't my question. One of the studies they did was scanning electron microscopy, correct?

MR. HUTCHINSON: He answered, Counsel.

THE WITNESS: Yes.

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Q (By Mr. Thornburgh) They also did FTIR, right?

A Right.

Q And FTIR looks at what?

A Functional groups within a certain molecule.

Q Okay. So polypropylene will have a fingerprint?

A Correct.

Q And degraded polypropylene will have carbonyl functional groups, correct?

A Oxidized polypropylene --

Q Oxidized polypropylene will have a carbonyl functional group or groups, correct?

A It can.

Q And where do those carbonyl groups fall within the FTIR spectra of oxidized polypropylene?

A It can range anywhere from the high 1600s to the high 1700s.

Q And they also performed differential scanning calorimetry, right?

A Correct.

Q Which showed a decrease in the heat of enthalpy. What does that mean?

A The amount of crystallinity -- the amount of

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energy required to break up the crystals in the crystalline material.

Q So with that -- so for oxidized polypropylene, you'd have a decrease in the heat of enthalpy, which would indicate that there are more amorphous regions on the material; is that fair?

A Correct, you might get more amorphous regions.

Q And amorphous regions are regions of a polymer which are more susceptible to oxidation or are oxidized?

A They can be more susceptible to oxidation than the -- than the crystalline domains, correct.

Q And melt temperature is another test that can be conducted, right?

A Sure.

Q And if there's a drop in the melting point of a polypropylene or polymer material, that's also an indication of oxidized polypropylene, correct?

A Not necessarily.

Q But if you take a pure polypropylene sample and you oxidize it and it degrades and you do melt-point temperature and it drops, that's clearly oxidized polypropylene?

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A No. No, it's not clearly. That is one explanation. The most likely explanation is that you have aliphatic ester compounds, which Dr. Jordi told us in Bellew come -- are actually inside the polypropylene filaments. They plasticize the material, and that is why you get a reduction in the melt temperature.

Q I wasn't -- I -- you must have misunderstood me.

A I don't think I did.

Q Intentionally oxidized pristine material, okay? If you take -- if you intentionally oxidize pristine material that's never been in a biological environment --

A Okay, sure.

Q -- and you get a FTIR score between 1600 and 1700s, that would be -- you could say that would be oxidative degradation or evidence of oxidative degradation, correct?

MR. HUTCHINSON: Object to form, Counsel. Are you talking about materials or you're talking about Prolene?

MR. THORNBURGH: Talking about polypropylene mesh, pristine -- intentionally --

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MR. HUTCHINSON: Polypropylene --
MR. THORNBURGH: Yep.
MR. HUTCHINSON: I'm sorry. Tell us for the record what you're talking about.
MR. THORNBURGH: Pristine polypropylene mesh --
MR. HUTCHINSON: Okay.
MR. THORNBURGH: -- that is intentionally oxidized.
THE WITNESS: Sure. As long as -- we can continue to have this debate as long as it's understood we're not talking about Prolene for -- you said polypropylene. That's what the Wood article talks about.
MR. THORNBURGH: I understand. You've been hired and you're being paid by Ethicon to defend its --
THE WITNESS: No, I'm telling you there is a --
MR. HUTCHINSON: I'm sorry, guys. Y'all need to -- one at a time. Dr. MacLean, you can go on.
THE WITNESS: I'm telling you there is a scientific difference, a significant

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scientific difference between Prolene and polypropylene. That's what I'm telling you. And the Wood article is square on that. It's polypropylene, not Prolene.
MR. THORNBURGH: We're going to look at all of the evidence --
THE WITNESS: Sure.
MR. THORNBURGH: -- okay? Because you have to look at the totality of the evidence, right?
THE WITNESS: Right. I'm just saying you have to be clear about the material you're talking about because if you put -- if you put Prolene in an oxidized environment and you put polypropylene in an oxidized environment, I'm not sure we're going to agree on some of the things that you're just about to say, so we just need to be clear.
MR. THORNBURGH: We're going to look at the totality of the evidence; we're going to --
THE WITNESS: Let's do it.
MR. THORNBURGH: -- explore it together.

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THE WITNESS: Let's do it.
Q (By Mr. Thornburgh) All right. So let's assume that you have a pristine polypropylene, Bard's material.
A We'll just call --
Q Does that make you feel better?
A No.
Q Or is that one of your clients?
A No, neither.
MR. HUTCHINSON: Hold on just a minute. Hey, Dan, excuse me --
MR. THORNBURGH: Hold on. Let me just run him through this.
MR. HUTCHINSON: No. Stop. No, we're not going to go forward like that if you keep up that line of questioning. Do you understand me?
MR. THORNBURGH: Let's --
MR. HUTCHINSON: Dan, do you understand?
MR. THORNBURGH: Let's do a different hypothetical.
MR. HUTCHINSON: All right. Is that question withdrawn?
Q (By Mr. Thornburgh) Polypropylene

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material manufactured by --
MR. HUTCHINSON: Dan, is that question withdrawn?
MR. THORNBURGH: No.
MR. HUTCHINSON: All right, well --
Q (By Mr. Thornburgh) Polypropylene material manufactured by Company X.
A We can just call it polypropylene material. Why don't we just call it neat, N-E-A-T, polypropylene.
Q Neat polypropylene --
A Good.
Q -- intentionally oxidized.
A Let's do it.
Q You're going to find a -- carbonyl functional groups within the -- according to you, the range of 1600 to 1700s, correct?
A Yeah, 1650 to high 1700s, correct.
Q All right. And if there's a drop in the heat of enthalpy, that's additional evidence of oxidized polypropylene, correct?
A I think it would be --
Q Amorphous?
A It would be evidence that you had some degradation of the polymer chains.

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Q Okay. And if you have a drop in the melt temperature, that's also evidence of or some evidence of oxidatively degraded polypropylene, correct?
A In that scenario, it would track.
Q And in this case, the Wood case, they performed all those studies and they found evidence of -- in fact, they report the results of infrared spectroscopy -- that's FTIR that we've been talking about, right --
A Correct.
Q -- demonstrated significant oxidation, right?
A That's their words, correct.
Q And additional studies, a differential scanning calorimetry, showed significant decrease in heat of enthalpy and melt temperature, right?
A Correct.
Q And so that would be indication or evidence of oxidized polypropylene, right?
A It is. That set of facts is consistent with oxidation. That set of facts is also consistent with other molecules that may be diffusing into the polymer.
Q And so if you turn the page -- turn the page.
A Okay.
Q Okay.

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A To which page?
Q The next page in the -- in the study. At the very top, it says, "Since the mid-nineties, the most common method of repairing abdominal hernias has been the tension-free repair using a variety of synthetic mesh such as polyethylene, heavy weight polypropylene, expanded polytetrafluoroethylene," and so on and so forth. And it goes on to say, "A large" -- down after --
A I'm with you.
Q -- Footnote 4 -- "A large subset of recurrence surgeries may be due to the lack of mesh inertness in vivo. These materials result in a large foreign body response that some thought was necessary to repair the defect. In recent years, there has been new evidence that a large foreign body response can result in physicochemical changes in the mesh material, which may lead to poor patient outcomes and recurrences. While synthetic mesh" -- let me just stop there for a minute.
You haven't gone out and looked at the entire body of literature concerning polypropylene -- strike that.
You haven't gone and looked at the entire

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body of literature concerning complications from polypropylene meshes, have you?
MR. HUTCHINSON: Object to form.
THE WITNESS: I can't say I've looked at the entire body of literature, correct, on that specific -- on that specific subject.
Q (By Mr. Thornburgh) In fact, you focused on -- just on polymer science, basically?
A Primarily, but I definitely looked at other -- I'll call them auxiliary topics related to this matter. I looked at some public literature that should be in my files.
Q And do you understand the difference between a clean contaminated area and a -- and a clean surgical site?
A Generally speaking, yes.
Q What's your understanding of the two?
A Repeat the question.
Q Do you understand what the difference is of a -- well, let me ask you this: The surgical site of the vagina, what type of environment is that? Is it aseptic, is it septic, is it clean, is it clean contaminated --
MR. HUTCHINSON: I'm going to -- hold on

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just a minute.
Q -- is it contaminated?
MR. HUTCHINSON: I'm going to object to the extent it's outside his expert report.
MR. THORNBURGH: Okay.
Q (By Mr. Thornburgh) You're not going to offer any opinions about that, are you?
A I'm not.
Q You didn't read any publications or literature concerning the different surgical site environments concerning contamination versus noncontaminated implant products, correct?
A I may have read something along those lines along the way. They did not come into my opinions.
Q So you didn't -- you haven't considered those medical issues in forming your opinion in this case; is that fair?
MR. HUTCHINSON: Object to form.
THE WITNESS: Can you repeat that question?
Q (By Mr. Thornburgh) Yeah. My question originally was...
(Discussion off the written record.)
Q (By Mr. Thornburgh) My question was: You

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didn't read any publications or literature concerning the different surgical site environments and the role that those environments play in implantable mesh devices?

A And I'd say my answer is, yes, I've read some literature along the way, but they did not -- they have not really -- they have not influenced my opinions.

Q Right. You read those, but you didn't consider those -- the differences or those publications that discuss the impact of the surgical site on the biomechanical properties of mesh devices, correct?

A I'm not sure what you mean by the word "consider." But I would say that they were certainly part of my institutional knowledge that I built up as I read through all of the literature.

Q Well, what is the significance of the environment in which a polypropylene material will be implanted? What's the difference between a clean contaminated versus contaminated field?

A Here's how I'll answer that to you. Here's how I'll answer that for you. There are a number of different molecules within the body -- lipids, esters, cholesterols, things of that nature -- that have a very specific chemical signature to them, chemical structure

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to them, which includes carbonyl formation -- or carbonyl functionality, rather. They have the ability, and Jordi has proven this, have the ability to diffuse into the filaments and cause a plasticizing effect. And all I'm saying is that mechanism has been proven to exist and there are -- there's direct results from that mechanism taking place.

Q Have you looked at any studies that differentiated between the biomechanical properties of implantable surgical devices of a clean surgical field versus a clean contaminated surgical field?

A I don't recall.

Q Did you consider that issue in rendering your opinions in this case?

A I don't believe that they came into my opinions.

Q It goes on -- if you look at the same page, page 1122 of the -- of Exhibit 8, 1122 of Exhibit 8, it goes on and says, "While synthetic mesh is frequently utilized to repair hernias, these materials are also being utilized in pelvic slings for urogynecologic applications. Unfortunately, these mesh materials, also composed of polypropylene, PET, and ePTFE, are experiencing biocompatibility problems which are

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resulting in groin pain and prolapse."

Did I read that accurately? Do you know where I'm at?

A I just -- I just caught up with you. Just tell -- just point to me on my document where you started reading from.

Q Right here (indicating) to right there (indicating). It says -- so let's just make sure we're on the same page. "While synthetic mesh is frequently utilized to repair hernias, these materials are also being utilized as pelvic slings for urogynecologic applications. Unfortunately, these mesh materials, also composed of polypropylene, PET, and ePTFE, are experiencing biocompatibility problems which are resulting in groin pain and prolapse."

A That's what it says.

Q Okay. And you didn't read -- you weren't focused on the biocompatibility problems which were causing groin pain and prolapse in patients who were implanted with polypropylene mesh devices for urogynecologic applications, correct?

MR. HUTCHINSON: Object to form.

THE WITNESS: No, because I'm not aware of any biocompatibility issues associated

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with Prolene.

Q (By Mr. Thornburgh) You're not aware of an biocompatibility --

A Biocompatibility issues associated with Prolene.

Q So you didn't -- you didn't seek out those publications?

MR. HUTCHINSON: Object to form. Mischaracterizes his testimony.

THE WITNESS: The record is clear that the Prolene material has been biocompatible since 1969.

Q (By Mr. Thornburgh) Do you know how many women have sued the client that you work for right now?

A No idea.

Q Do you know what complications rate for pelvic organ prolapse have been -- sorry, strike that.

Do you know what Ethicon's own internal scientists have found?

A Regarding?

Q Strike that.

Do you know what Ethicon's key opinion leaders have found or have you considered the publications by Ethicon's key opinion leaders

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concerning complications associated with Prolene pelvic organ prolapse devices?
MR. HUTCHINSON: Object to form.
THE WITNESS: No, my work is not focused on any of those so-called or alleged complications.
Q (By Mr. Thornburgh) You didn't -- you didn't read all of the publications that discuss that, right?
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) That wasn't your focus?
A That --
Q Your focus wasn't --
MR. HUTCHINSON: Excuse me. One at a time. Dr. MacLean, you can finish answering the question.
THE WITNESS: That was not within my scope of work.
Q (By Mr. Thornburgh) So you are not offering opinions concerning the complication rates or the biocompatibility issues of Prolene mesh devices, correct?
A Again, I'm not aware of any biocompatibility issues. And, no, I'm not offering any opinions about any type of complication rate.

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Q Are you aware that -- if you go on to the next sentence -- we're not done yet -- on July 13th, 2011, the FDA issued a statement warning surgeons and patients about the complications associated with surgical meshes?
MR. HUTCHINSON: Excuse me, Dan. What page are you on?
MR. THORNBURGH: Same page, just --
MR. HUTCHINSON: One twenty?
MR. THORNBURGH: One twenty-two [sic] of Exhibit -- page -- the very top right-hand corner says 122 [sic] of Exhibit No. 8, and we're halfway through the left column all the way down.
MR. HUTCHINSON: I'm sorry, but that's page --
MR. THORNBURGH: I might have a different page number.
MR. HUTCHINSON: So the document -- I think you're reading from page 114 [sic].
MR. THORNBURGH: Just the second page of the -- the second page of Exhibit 8.
MR. HUTCHINSON: Okay. You're saying --
MR. THORNBURGH: Left-hand column.

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MR. HUTCHINSON: You're saying 122 and it's not 122. It's 114 [sic].
MR. THORNBURGH: I'm sorry. 1114. I was looking at the wrong side.
MR. HUTCHINSON: That's fine.
MR. THORNBURGH: 1114.
MR. HUTCHINSON: That's fine.
Q (By Mr. Thornburgh) See where it says, "On July 13th, 2011, the FDA issued a statement warning surgeons and patients about the complications associated with surgical mesh"? Did you read the FDA warnings?
A Which warnings?
Q Did you read the FDA statement warning surgeons and patients about complications associated with surgical mesh?
A No, I did not.
Q Because you keep on saying, "I'm not aware of any biocompatibility issues."
A Correct.
MR. HUTCHINSON: Hold on just a minute. I'm sorry, is that a question?
MR. THORNBURGH: Yeah.
Q (By Mr. Thornburgh) So -- but you --

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MR. HUTCHINSON: All right. I'm sorry. Just, Dan, if you could phrase your comment to a question, that would be helpful.
Q (By Mr. Thornburgh) So you aren't aware of the -- strike that.
It goes on to say, "More recently, the FDA is considering reclassifying urogynecologic surgical mesh used to repair pelvic organ prolapse from Class II to Class III." Do you see that?
A I do.
Q "Synthetic meshes are recognized as foreign bodies and thus are subjected to various enzymatic attacks by the body."
Do you know what they mean by "enzymatic attacks by the body"?
A I do. That's part of the foreign body response when the implant goes inside the body.
Q What is -- what is -- what is the foreign body response to the implantable foreign object? Strike that.
How does the body respond to the foreign body?
A Okay. Look, this is not my area of expertise, but I'll tell you what I've learned through

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reading the literature, that once you put the implant inside the body, proteins arrive at the site, enzymes arrive at the site, macrophages arrive at the site, foreign body giant cells actually get developed over time that ultimately turns into scar tissue and collagen and forms a network of tissue that embraces the mesh within the existing -- within the existing surrounding tissue.

Q Do you know what frustrated phagocytosis is?

A I read the term. I just can't recall what it means at this moment.

Q The immune response to the foreign body is to try to get rid of it, right?

A That's the foreign body response of the body, correct, of the human body.

Q And it does that by sending in its troops, right, it sends in macrophage --

A Yeah, all the things that I just described.

Q Giant cell multinucleated foreign body --

A Generally speaking, yes.

Q Uh-huh. And there are chemicals that are -- that are produced during this immunologic response to the foreign body, the mesh, correct?

A Correct.

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Q And those chemicals include superoxides and oxidized -- and peroxides?

A Correct.

Q And peroxide and superoxides are the body's way of trying to -- during the frustrated phagocytosis, to try to gobble up the foreign material to get rid of it, expel it from the body, right?

MR. HUTCHINSON: Object to form.

THE WITNESS: Generally speaking, yes.

Q (By Mr. Thornburgh) And peroxides and superoxides are oxidizing agents, correct?

A They can be.

Q And oxidizing agents can oxidize polypropylene?

MR. HUTCHINSON: Object to form.

THE WITNESS: It can oxidize polypropylene. Oxidizing agents -- certain oxidizing agents can oxidize polypropylene.

Q (By Mr. Thornburgh) Especially when the inflammatory response is chronic, right?

MR. HUTCHINSON: Object to the form. Counsel, you've asked him several questions about biocompatibility, and he's told you he's not an expert in that area.

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THE WITNESS: Can you just repeat that last question?

Q (By Mr. Thornburgh) Well, I said -- you said that -- you agreed that oxidizing agents -- that certain oxidizing agents can oxidize polypropylene, and I said especially when the inflammatory response is chronic.

A If the oxidizing environment is persistent, then it has the potential to consistently -- or persistently oxidize the polypropylene.

Q Because it's a vicious cycle, right?

MR. HUTCHINSON: Object to the form.

Q (By Mr. Thornburgh) Of the macrophages that's causing this invasion in the tissue, right?

A Sure.

MR. HUTCHINSON: Object -- hold on just a minute, Dr. MacLean. Object to form.

THE WITNESS: That hypothetical is true; however, that is exactly why there are antioxidants in the Prolene formulation to combat the environment that you just described, and we know it does it successfully.

Q (By Mr. Thornburgh) Do you know Dr. Wood?

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A I do not.

Q Do you know Dr. Bachman or Dr. Grant?

A I do not.

Q Do you know Dr. Ramshaw?

A I do not.

Q You've never heard of Dr. Ramshaw, polymer scientist, been studying the degradation of implantable polypropylene meshes for the better part of 25 years?

MR. HUTCHINSON: Object to form.

THE WITNESS: Are you asking me if I know him or have I heard of him?

Q (By Mr. Thornburgh) Do you know?

A I do not know him.

Q Have you heard of him?

A I've heard of him.

Q Do you understand that he's been studying degradation of polypropylene meshes, including Prolene meshes, for the better part of 25 years?

MR. HUTCHINSON: Object to form.

THE WITNESS: I believe so.

Q (By Mr. Thornburgh) You started studying it -- let me ask you this question: When did Ethicon's lawyers hire you in this case?

A I think we were retained with a verbal

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agreement sometime in May and retained in early June.
Q Okay. So these polymer scientists and biological -- and the department of biological engineering at the University of Missouri, that's a -- that's a good school, right?
A I don't have any -- I don't have any opinion on that school one way or the other.
Q Do you know about its polymer science program?
A Not specifically.
Q Do you know about its mesh investigations?
A Not specifically.
Q Do you know about the work that the school and these scientists have done with Ethicon?
A I may have read it somewhere, but not specifically.
Q Did Ethicon show you any internal documents concerning Dr. Ramshaw and Ethicon's consulting work with Dr. Ramshaw to investigate whether or not Prolene degrades?
MR. HUTCHINSON: Object to form.
THE WITNESS: I don't remember.
Q (By Mr. Thornburgh) If Ethicon had internal documents concerning studies that were being conducted

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by Dr. Ramshaw and his colleagues at the University of Missouri paid for by grant of Ethicon, you would expect Ethicon and Ethicon's lawyers to provide those to you, right?
A They may have been part of the production. I just don't remember.
Q These scientists go on to say, "Synthetic meshes are recognized as foreign bodies and thus are subjected to various enzymatic attacks by the body. The primary attack on the material is from neutrophils and macrophages, which are stimulated upon injury or implantation. The cells release lysosomal enzymes." Do you know what lysosomal enzymes are?
A Yes. They're protein.
Q You're saying that lysosomal enzymes are a type of protein?
A Enzymes are protein, so yes.
Q And then they -- and oxidants, do you see that?
A I do.
Q That can actively break down some of the mesh material?
A Yeah.
Q Okay, you disagree with that?

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A I don't disagree with that.
Q You agree that -- you agree with that statement?
A Just repeat that last piece. I want to make sure we're saying the same thing.
Q Yeah, that the primary attack of -- on the material is from neutrophils and macrophages, which stimulated -- which are stimulated upon injury or implantation. The cells release lysosomal enzymes and oxidants that can actively break down some of the mesh materials.
MR. HUTCHINSON: Object to form.
THE WITNESS: Right, and I would say in the -- in the context of Prolene being the implanted material, I don't agree with that.
Q (By Mr. Thornburgh) You agree that for other polypropylene materials manufactured by other manufacturers for the use as urogynecologic mesh devices, that those materials may break down as a result of the oxidative attack through this immunologic response, but not Prolene, right?
MR. HUTCHINSON: Object to form.
THE WITNESS: I haven't studied any

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other mesh material besides Prolene, with the exception of the other candidate materials that Ethicon had looked at in their studies in the '80s and '90s.
Q (By Mr. Thornburgh) Like PVDF?
A Correct.
Q "The resulting degradation inflicted on the mesh and the resulting effect on the patient is a subject which requires investigation in order to understand the mesh material-patient interactions and ultimately improve future mesh-material designs," right?
A That's what it says.
Q This is dated 2013, right?
A Yep.
Q And we're going to get to the Ethicon studies in a moment.
A Great.
Q But those internal Ethicon studies from the 1980s and 1990s, to your knowledge, were never published to the general medical and scientific communities, correct?
A No. They're internal documents, to my knowledge. It might have been very helpful for them to

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know that.
Q And if you turn to page 1116. See the SEM section? 1116.
A Yes, I do.
Q "SEM micrographs can be seen in Figure 2. Micrographs of the pristine polypropylene mesh displayed relatively smooth surfaces with signs of extrusion while explanted polypropylene showed signs of crazing/surface cracking which is indicative oxidation."
You would agree with me that crazing and cracking is indicative of polypropylene oxidation, right?
MR. HUTCHINSON: Object to form.
THE WITNESS: It can be if you're -- if you've assured yourself that the material you're looking is polypropylene, oxidized polypropylene.
Q (By Mr. Thornburgh) It has cracks that run perpendicular to the extrusion lines, right?
MR. HUTCHINSON: Object to form.
THE WITNESS: Oxidized polypropylene, if oxidized enough and degraded enough, can ultimately manifest in cracking.

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Q If you go to the --
MR. THORNBURGH: How much time do we have left?
THE VIDEOGRAPHER: Two minutes.
Q (By Mr. Thornburgh) If you go to the "ATR-FTIR," have you run any ATR or FTIR experiments on polypropylene Prolene mesh material?
A Yes, I've run IR on exemplar Prolene material.
Q Is that contained within your --
A It is.
Q -- Exhibit 5?
A It is.
Q Okay. Have you run any IR on explanted polypropylene material?
A I have not. Many others have, and that data I have reviewed.
Q It goes on to say, "The scans revealed" -- and I'm talking about FTIR -- "The scans revealed a large peak" -- we're talking about polypropylene, right? "Figure 3 shows representative spectrum collected from the explanted polypropylene mesh along with a spectrum of pristine polypropylene mesh." Looking at the control, right?

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A Uh-huh.
Q Looking at explanted material, testing it with -- against the control, which is the pristine, unused mesh right out of the box, right?
A That is correct.
Q "And the scan revealed a large peak at 1740 centimeters, indicative of carbonyl groups (CO), that was not evident in the pristine sample. This correlates with free radical formation and oxidation of the polypropylene mesh while in vivo." Did I read that correctly?
A You read that correctly.
Q And if we turn the page, we have Exhibit -- we have Figure 2, which shows the pristine Prolene mesh as -- in Figure A and D as the explanted mesh that was analyzed using scanning electron microscopy, right?
A Correct.
MR. THORNBURGH: We have to change the tape.
THE VIDEOGRAPHER: We are now going off the video record. The time is currently 12:28 p.m. This is the end of Tape No. 2.
(Lunch recess taken.)
THE VIDEOGRAPHER: We are now back on

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the video record with Tape No. 3. The time is currently 1:37 p.m.
Q (By Mr. Thornburgh) Hi, Doctor. Before we took our lunch break, we were talking about the Wood article. Doctor, what are free radicals?
A Free radicals are when -- for example, when you take a peroxide that's in the neighborhood of a polypropylene or a polyethylene type polymer, it actually can create a free radical or basically a free proton or electron on the polymer that gives it the ability to react with other molecules.
Q And a free radical can degrade the polypropylene, correct?
A A free radical can attack the polypropylene chain, correct.
Q Attack it and degrade it, right?
A Correct.
Q And that can be without oxygen species, right?
A You can create -- yes, you can do -- you can have thermal oxidation, for example, where you just have too much heat put into the polymer. That can break a polymer bond, covalent polymer bond, latch on to available oxygen that's just in the air, for

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example, and can cause oxidation. That's possible.
Q And that's what was -- that's the mechanism of degradation that's described in the Wood article, correct?
A Yes, that free radicals are formed in the presence of peroxides.
Q And when we went off the record, we were looking at the scanning electron microscopy images on page 1117 of Exhibit 8. And you see that the Figure 2A is the pristine polypropylene mesh that was analyzed, and D is the explanted polypropylene mesh that was analyzed, correct?
A Correct, that's what it says.
Q And you can see in Exhibit D surface changes or cracking in the surface of the polypropylene fibers, correct?
A No, I would not say that that's conclusive that that is cracking in the polypropylene.
Q Well, we've got cracking in the image and we also have the FTIR carbonyl group to the right of the -- or just below the images, which shows a carbonyl peak at 1740, correct?
A Correct. But as we talked about earlier, the cleaning was not successful.

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Q It's your opinion that the cleaning was not successful?
A It's not my opinion. It's actually -- it's in the -- it's in the report.
Q Do you have an opinion whether or not the polypropylene -- strike that.
Do you have an opinion that the conclusions in the Wood article are incorrect and that the polypropylene did not actually oxidize?
A I think the data says it's inconclusive that it was an oxidation mechanism that caused that cracking.
Q And so you disagree with the conclusions of the Wood scientist, correct?
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) You disagree with the authors of the Wood article, correct?
MR. HUTCHINSON: Same objection.
Q (By Mr. Thornburgh) If you turn to --
A I disagree with their definitive conclusion that it was oxidation.
Q And if you turn to page 1120 of Exhibit 8, it says, "Unfortunately, polypropylene will degrade in an oxidizing environment, such as the environment during a

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foreign body response. Because of this, polypropylene has been shown to oxidize in vivo."
Do you agree or disagree with those statements?
A What page are you on?
Q Page 1120 of Exhibit 8 under "Polypropylene."
A I agree that polypropylene can degrade in an oxidizing environment. I agree with that statement.
Q And do you agree that oxidation of polypropylene results in surface crazing and cracking, changes in the mechanical strength, and increased brittleness?
A I agree with those things. Yes, that's all -- that's all correct.
Q And it goes on to say, "The SEM image shown in Figure 2D demonstrates obvious crazing and cracking of the explanted polypropylene specimen as compared to the pristine." Do you disagree with that?
A I disagree with -- if you interpret that as -- if you interpret that as the crazing and cracking is definitively taking place in polypropylene and no other material, then I disagree with that.
Q The authors go on to say that the -- "Additionally, ATR-FTIR spectra in Figure 3 confirmed

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the presence of carbonyl peaks which are indicative of surface oxidation."
Do you agree or disagree with that statement?
A Neither. I'd say that that's only part of the potential reasoning that those carbonyl peaks would be present. As I mentioned earlier, there are other species that are available in vivo that are going to have carbonyl functionality to them. And this -- these authors have not ruled out those additional molecules that we know are present.
Q Did you also note that these authors also performed additional studies, the -- you see the MDSC data displayed in Figure 6?
A Yes, I do.
Q And did you also note that the authors found that the explanted samples displayed a lower heat effusion and lower melt temperatures?
A Correct, but I explained earlier that that lower -- that lower melt temperature can also be assigned to having the material being plasticized.
Q By -- when you say "plasticized," are you talking about the formaldehyde-protein bond?
A I am not.
Q What are you talking about?

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A I'm talking about the ester-based molecules that Dr. Jordi found and was able to extract out of filament in the Bellew matter that clearly tell us that the material is being -- that the material is being plasticized. So that is the diffusion of small aliphatic ester molecules into the material that's causing it to increase its toughness, increase its flexibility, and suppress its melt temperature.

Q So you disagree with the Wood authors that these findings were indicative of chemical changes within the bulk structure of the material?

A Where are you? Where did you cite that from?

Q It's the next sentence after the heat of effusion and low melt temperature sentence that we just read on page 1120.

A I don't disagree that that's what they got for data. I disagree that you can affirmatively ascribe that behavior to oxidation and solely oxidation.

Q If you turn to 1121 under the conclusions.

A Uh-huh.

Q Are you there?

A I am.

Q It says, the second sentences, "The

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polypropylene mesh demonstrated chemical degradation via oxidation, permanent distortion of the mesh, and changes in thermal properties." It goes on to say, "While the results of the characterization study showed that polypropylene will undergo oxidation."

Do you disagree with those conclusions from these authors?

A I disagree that those are the only way to get the changes that they observed, by -- oxidation is the only way to get to those changes.

Q Dr. Thames testified in the Bellew case starting on page 83, line 7 -- strike that.

If you turn to page 84 --

MR. HUTCHINSON: Counsel, do you have a copy for us?

MR. THORNBURGH: No. I'm happy to show you.

Q (By Mr. Thornburgh) Eighty-four, line 1, question: "Well, Doctor, you've testified previously regarding -- remember looking at the Wood article?"

"Yes, sir." Answer: "Yes, sir, I do."

Question: "Which is another polypropylene mesh?"

"Yes, sir."

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"Used FTIR?"

"Yes, sir."

"FTIR to determine whether or not that mesh had degraded?"

"I do. The Wood article, now, we're talking about."

"All right." Question: "All right. And you've testified that in that study, the mesh did degrade as a result of oxidation, and the band at 1740 confirmed that it had degraded as a result of oxidation, correct?"

Dr. Thames' answer: "I did."

Page 85, line 7, "Dr. Wood found a carbonyl peak on FTIR of oxidized degraded polypropylene mesh at 1740, right?"

"That's correct, sir."

Question: "And you agree that the polypropylene mesh had degraded as a result of oxidation, correct?"

Answer: "That's correct, sir."

"Do you disagree with Dr. Thames" --

MR. HUTCHINSON: I'm going to object --

Q -- "your colleague, an expert in this case?"

MR. HUTCHINSON: I'm going to object to

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form to the extent you've asked the witness to interpret a segment of a deposition transcript and especially without showing him the copy of the deposition.

MR. THORNBURGH: No speaking -- you get to object.

MR. HUTCHINSON: Then that's my objection.

Q (By Mr. Thornburgh) I'll show it to you. "And Dr. Wood found a carbonyl peak on FTIR of oxidized degraded polypropylene mesh at 1740, right?"

"That's correct, sir."

Question: "And you agree that the polypropylene mesh had degraded as a result of oxidation, correct?"

"That's correct, sir."

Question: "As confirmed by the peak at 1740?"

Answer: "Correct."

You disagree with Dr. Thames's opinion regarding the Wood article and the conclusions of the Wood scientists and researchers?

A I --

MR. HUTCHINSON: Same objection.

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THE WITNESS: I disagree that that is the sole explanation for the changes that had taken place in the Wood article.

MR. THORNBURGH: We're done with Exhibit 8.

Q (By Mr. Thornburgh) You reviewed some other -- some internal documents from Ethicon, correct, some internal Ethicon documents?

A I -- yes, hundreds.

Q And the Ethicon internal documents that you reviewed were selected and provided to you by Ethicon's lawyers, correct?

A Again, they sent me waves of documents, and along the way I may have asked for more information, so I wouldn't say it was a one-way street.

Q Well, what things did you ask for?

A I don't recall.

Q What types of things did you ask for?

A I don't recall. I just remember reviewing documents. We'd have some conversations. I may have asked for more information and they may have provided it.

Q Well, what things were produced to you by Ethicon's attorneys?

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A Whatever is listed in my files reviewed.

Q So the case-specific materials, the internal Ethicon documents, right?

A Correct. You can go to that second appendix in my document; it will list exactly what they sent me.

Q The expert reports, correct?

A Correct.

Q The depositions?

A Correct.

Q Which depositions did you read in this case?

A Guelcher's, one or two Iakovlev depositions, Jordi deposition, Thames' Bellew deposition. Those are the ones I remember off the top of my head.

Q Did you read any depositions of the -- of any of Ethicon's internal employees or former employees?

A Yes. I recall --

Q Which --

A -- reading Thomas Barbolt's deposition.

Q Which -- one volume, two volumes, three volumes? How many volumes did you read?

A I don't recall.

Q You didn't read six volumes of deposition testimony from Dr. Barbolt, did you?

A I don't -- no, I don't remember -- I don't remember reading six volumes of his testimony.

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Q So you only read whatever volumes were provided to you by Ethicon, correct?

A Or they could have provided all the volumes to me and I may have skimmed some and read some.

Q And they provided you with some of the literature?

A Some literature. A lot of the literature we found on our own, but some of the literature came from them.

Q They provided you with Wood article, the Clave article, the Costello article, the Mary article, right?

MR. HUTCHINSON: Objection. Compound.

THE WITNESS: I just -- they could have. I just don't recall. Again, just look at the list and it will tell you what they sent me.

Q (By Mr. Thornburgh) The materials that Ethicon's lawyers chose to provide you and which you are relying on are listed in your report at the index, right?

A Correct.

Q Appendix C?

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A Correct.

MR. HUTCHINSON: Object to form.

Q (By Mr. Thornburgh) And what was the purpose of -- what did Ethicon ask you to do in this case, or Ethicon's lawyers?

A I think we've talked about it a couple of times. They asked me to take a look at the universe of documents that they provided, many of which of them are Ethicon documents, internal documents, internal studies, external studies, public literature, all the things that we've talked about, synthesize and review that information and determine, to the best of my ability, if the Prolene material is being degraded by some sort of oxidative degradation mechanism.

Q Did they -- they also asked you to run some studies at your lab?

A They didn't ask. I actually had proposed that work to them.

Q Okay. And if we -- in Exhibit No. 2, do you have the work that you performed at your -- at your lab or which was performed on your behalf?

A Are you asking me if I have the --

Q The microscopic work that you did.

A Yes, I have -- I have that report in front of

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me.
Q Okay. And what did -- what did Exponent do to test -- what types of studies did Ethicon do on the polypropylene/Prolene TVT mesh exemplars that were received from Ethicon?
A You said "Ethicon" in the beginning of that sentence.
Q Sorry. What did Exponent do? What studies did Ethicon conduct?
A Okay. Well, we set up an experiment to really test three hypotheses. The first hypothesis was does oxidized or unoxidized polypropylene stain with H&E staining. The second hypothesis was does H&E stain have the ability to mechanically trap, as posited by Dr. Iakovlev. And the third is can you manipulate polarized light to get artifacts that might suggest some sort of bark layer that really isn't there.
Q Okay. So you were asked to check the -- to test the hypothesis does oxidized or unoxidized polypropylene stain with H&E staining?
A Correct.
Q The hypothesis -- also, the second hypothesis was does H&E stain have the ability to mechanically trap as deposited?

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A As posited.
Q As posited by Dr. Iakovlev. And the third was can you manipulate polarized light to get artifacts that might suggest some sort of layer. Is that what your -- the scope of your testing was?
MR. HUTCHINSON: And, Counsel, just so we're clear, on the first hypothesis that you were asking about, were you asking about unoxidized polypropylene or Prolene? I didn't hear you correctly.
MR. THORNBURGH: Hold on. I asked him what studies he did --
MR. HUTCHINSON: Okay.
MR. THORNBURGH: -- and he told me --
MR. HUTCHINSON: Okay. I'm just -- I'm just --
MR. THORNBURGH: -- that those were the three studies he did.
MR. HUTCHINSON: I didn't -- I didn't understand what you said.
MR. THORNBURGH: He was testing three hypotheses.
MR. HUTCHINSON: Okay, my bad. And what was the first one, my question?

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MR. THORNBURGH: Well, can I get the court reporter to read it back.
MR. HUTCHINSON: I just want to know what the first hypothesis was.
MR. THORNBURGH: The first -- sorry, can I go ahead and read it?
(Discussion off the written record.)
MR. HUTCHINSON: I just want to know if you said polypropylene or Prolene. That's all I'm wanting to know. I just didn't hear you.
MR. THORNBURGH: I asked the witness what Exponent was asked to do or what they did. The response was, "We set up an experiment to really test three hypotheses. The first hypothesis was does oxidized or unoxidized polypropylene stain with H&E staining. The second hypothesis was does H&E stain have the ability to mechanically trap, as posited by Dr. Iakovlev. And the third is can you manipulate polarized light to get artifacts that might suggest some sort of layer" --
MR. HUTCHINSON: Okay.

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MR. THORNBURGH: -- "that really isn't there."
MR. HUTCHINSON: That's all I want to know.
THE WITNESS: Okay. Yeah.
Q (By Mr. Thornburgh) Okay. And --
A And I just -- I just need to clarify for the record. I should have said Prolene. It's in the report. When I said polypropylene earlier, the hypothesis testing unoxidized and oxidized Prolene.
Q Now, I'm correct that Ethicon adds antioxidants to their resin, correct?
A Correct.
Q And you had talked about primary and secondary antioxidants?
A Correct.
Q And we're going to talk about some documents, but we're also going to talk about your expert report that we've -- and your testing. But are there three types of -- how many different types of additives are used in polypropylene devices to prevent oxidation?
A I'm not sure I understand your question.
Q What are the different types of -- you talked about primary and secondary antioxidants. Are those

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the only antioxidants that are used to retard oxidation and degradation?
A Those are two specific types. One is DLTDP and one is a thioester. So the first one is a hindered phenol antioxidant used in a lot of olefin materials, including polypropylene. It's a hindered phenol. That is a primary and that is a radical scavenger, free-radical scavenger; and then the thioester, which is the DLTDP.
Q Is what?
A Secondary.
Q And what is the -- what is -- what's the difference between primary and secondary?
A Well, primary antioxidant is actually -- we talked about the free -- the free radicals that actually take place in the chemistry. They are free-radical scavengers, so they go out and actually bond or bind onto those free radicals that are generated to stop that autocatalytic reaction that we talked about earlier.
The thioester is the secondary additive, and that goes out and actually neutralizes, chemically neutralizes those peroxides that can cause the free radicals to form. So it's kind of a double-fisted

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approach, if you will.
Q What are thioesters?
A I just answered that.
Q I didn't understand your description of it.
A They are small molecules that go out and find peroxides and neutralize them so they can't cause subsequent damage to the polypropylene.
Q Okay. And what is -- what's your understanding of Ethicon's primary antioxidant?
A Santanox R, which is the hindered phenol that we talked about a few minutes ago.
Q And what's the basis for your understanding that the Santanox R is the primary antioxidant used by Ethicon?
A Because that's how it's discussed in the polymer literature, that it's the primary antioxidants that goes off and basically latches on to those free-radical sites that we talked about and stops that autocatalytic oxidation process.
Q And the secondary is DLTDP?
A Correct.
Q That's your understanding. And what's the basis for that understanding?
A Same discussion, it's just -- well, that's

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how it's referred to and documented in the scientific literature. And again, they're synergistic, they're working in harmony, they're working together to combat those two mechanisms that we talked about.
Q And what is Ethicon's thioester?
A It's the DLTDP.
Q And the basis for that opinion or understanding?
A It's -- I got it from there -- Ethicon's literature, Ethicon's internal documents. That's the antioxidant -- that's the secondary antioxidant that they use in the formulation of Prolene.
Q And the reason why Ethicon -- the reason why -- well, is it your understanding that the reason why Ethicon uses Santanox and DLTDP is because polypropylene will degrade without a retarding additive?
A In certain oxidizing environments, it has that potential, and that's why you put the antioxidants in it, to negate that potential.
(Exhibit 9 marked for identification.)
Q (By Mr. Thornburgh) I'm handing you what I've marked as Exhibit No. 9, which is the February 21st, 2003 Ethicon internal document and a --

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attached to the email is a report by Dr. John Karl. Have you seen this document before?
A I believe I have.
Q You see on the -- on the email from February 2003, February 21st, 2003, the first page of Exhibit 9, there's a discussion about what the -- what are the additives within the Prolene resin. And if you look to the last paragraph, it says, "If there is any biocompatibility and/or safety documents for Prolene, it should have addressed the additives and made some worst-case estimates."
Did you look at any internal documents or internal studies testing the internal additives of the Prolene resin to determine biocompatibility?
A Sure. I've seen several documents that support the biocompatibility of the material.
Q My question was: Did you specifically review any documents that looked at the biocompatibility of the additives that are contained within the Prolene resin?
A Well, that would be part of the testing program. When I'm -- when I'm testing Prolene for biocompatibility, I'm testing the entire formulation, which would include the additives that we just talked

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about.
Q My question was: Did you review any internal Ethicon documents that looked at -- specifically looked at the biocompatibility of the Prolene additives, including Santanox R and Procol?
MR. HUTCHINSON: Object to form. Been asked and answered, Counsel.
THE WITNESS: Yeah, it's the same answer.
Q (By Mr. Thornburgh) You're not answering my question. My question was: Did you look at -- specifically look at any testing of the Santanox R or the Procol LA?
A Oh, I don't recall if there's any testing that was isolated to the additives themselves, but the testing that was done would have included those additives in it because they are part of the Prolene formulation.
Q Aren't there requirements under the 10993 -- ISO 10993 requirements and guidelines to test the additives that are within a permanent implantable mesh material?
A There are, but the specific pieces of 10993 that you test to is often negotiated with FDA. So it's

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very material and application specific.
Q That wasn't my question. My question was: There are requirements to test the additives of permanent implantable devices, correct?
MR. HUTCHINSON: Object to form.
THE WITNESS: There is a test within the standard that -- there's a test within the standard that does call out testing of additives, correct.
Q (By Mr. Thornburgh) And the purpose for that is because additives can leach out of the implantable or implanted medical device, correct?
MR. HUTCHINSON: Object to form.
THE WITNESS: I think that is -- yes, that's one of the reasons why that test is done or can be done, correct.
Q (By Mr. Thornburgh) And those additives would include the Santanox R, the DLTDP, and the Procol LA-10, right?
A Those are some of the additives in the formulation, correct.
Q And do you agree that the additives, including the Santanox R, the Procol LA, the DLTDP, the calcium stearate, and the CPC pigment, can leach out of

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the protein fibers?
MR. HUTCHINSON: Object to form.
THE WITNESS: I have not seen any data that suggests that that's happening.
Q (By Mr. Thornburgh) Did you read any depositions that -- by Ethicon's witnesses who tested for leaching who concluded that the additives in the Prolene device and the TVT device do leach out of the Prolene fibers?
MR. HUTCHINSON: Object to form.
THE WITNESS: I don't recall seeing that data. I need to see a -- I need to see a document.
Q (By Mr. Thornburgh) Did Ethicon show you that deposition?
A I don't recall. I remember -- I remember Tom Barbolt making some of those comments in his deposition. I don't recall seeing any test data or supportive information.
Q You understand that Dr. Barbolt was the person responsible for --
A I do.
Q -- for overseeing those studies?
A I do.

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Q So you would rely on Dr. Barbolt concerning whether or not Santanox or Procol or DLTDP can leach out of the fibers, right?
MR. HUTCHINSON: Object to form.
THE WITNESS: I would not rely on him. I'd want to see the data myself.
Q (By Mr. Thornburgh) You haven't seen the data?
A I don't recall seeing the data. If you have a document that suggests that or has test data that talks about leaching, I'd be happy to review it, but I just don't recall seeing it.
Q So you don't have an opinion one way or the other?
A As we sit here today, no, but I have not seen any data that suggests that.
Q Did you ask the -- Ethicon's lawyers or Ethicon to provide you with any documents that would demonstrate whether or not DLTDP, Santanox R, Procol LA, or the other additives would leach out of the -- of the Prolene fibers?
A I don't recall asking them that.
Q If the additives leach out of the Prolene fibers in the TVT, including the antioxidants, that

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could leave the mesh fibers, the Prolene fibers, susceptible to degradation, correct?
A Not necessarily.
Q Not necessarily?
A Correct.
Q Well, if there's a certain amount that's put in to protect against degradation and over time, inside the body, those additives leach out of the Prolene fibers, that would increase the risk or the susceptibility to oxidative degradation, correct?
A It depends on the rate it's happening. It depends on the time scales we're talking about. Let's just say, for example, hypothetically that leaching is occurring and there is some migration of these molecules out of the fiber. That still doesn't mean that there's plenty still within the fiber to do its job. These things are not put in -- these things are put in in surplus so that they give a long-term effect.
So you would have to convince me that -- A, that they're leaching out, and B, that they've leached out enough to actually leave the material unprotected. And there's no such data that I've seen.
Q Are you offering any opinions in this case regarding the cytotoxicity of the TVT material?

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A No, I'm not.
Q You're not going to come in and testify that the TVT is not cytotoxic?
A I'm not going to offer that opinion. I have not offered that opinion in my report.
Q You haven't reviewed any of the cytotoxicity testing, correct?
A Well, no, I've reviewed a lot of those documents. Yeah, I mean, there's rabbit studies, there's -- there is rat studies. I believe there's a dog study. So I've seen a lot of those documents. I've reviewed them, synthesized them, but I'm not offering any opinions on them.
Q Did you see the ISO lesion testing done of the TVT Olmstead device which showed that it was severely cytotoxic?
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) The mesh?
A I did, but I also saw a couple of follow-up reports that refute that data. I think there was a lot of issues with how -- how much integrity was behind that data and how it stacked up with other labs.
Q You haven't conducted any cytotoxicity testing of the TVT device, correct?

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A I have not.
Q And you haven't looked at the clinical studies of the Prolene polypropylene mesh devices, correct?
A I just don't remember. I don't remember if I've -- it was not a focus of my work. So if I saw them, I just don't remember them.
Q In order for you to form an opinion about cytotoxicity and whether or not it's cytotoxic, the polypropylene or the additives within the polypropylene, you'd have to do a full review of the literature to determine the rate of complications associated with the product, right?
MR. HUTCHINSON: Object to form. Counsel, he's not offering cytotoxicity opinions.
MR. THORNBURGH: It's in his report, so...
THE WITNESS: Where is it in my report?
MR. THORNBURGH: Go to Exhibit 2. If you're not offering it, you're not offering it. I'm fine with it. I just want to make sure I understand what you're doing.
Q (By Mr. Thornburgh) "Prolene

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Biocompatibility," do you see that section?
A What page are you on?
Q On page 20. It's the very last paragraph, "In order for Prolene mesh to be used as a permanent tissue implant, Ethicon must comply with ISO 10993 and analyze the cytotoxicity, sensitization, and genotoxicity, among other tests" --
A Yes.
Q -- "of the Prolene mesh. The safety of the Prolene mesh has been demonstrated through a long history of clinical use of Prolene sutures."
You haven't looked at the long history of clinical use of Prolene suture -- of the Prolene TVT device?
A If the clinical studies that you're referring to are the rabbit, the dog, the rat studies, et cetera, then I have looked at those documents.
Q You understand that those are pre-clinical, right? Do you understand the difference between pre-clinical and clinical?
A I do.
Q Pre-clinical are studies that are done on animals?
A Correct.

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Q Generally short-term studies?
A Right.
Q Don't demonstrate safety or -- safety or effectiveness in humans?
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) Right?
A Correct. But you have to realize I am actually just citing an internal Ethicon document that --
Q Well, I --
A -- refers to those clinical studies.
Q I just want to know if you're going to offer opinions about cytotoxicity at the trial in this case.
A I'm not.
Q And you're not going to -- and you're not going to rely on that data for any opinions in this case, right?
A No, I'm not. I'm just stating that the material has been demonstrated to be biocompatible since 1969. It's been tested over and over and over again, and it's the same conclusion that it's biocompatible. That's all I'm saying.
Q Do you understand the general principles in -- with regard to biocompatibility or foreign --

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strike that.
Do you understand the general principle that the greater the surface area of a foreign body, the greater inflammatory response?
MR. HUTCHINSON: Object to form.
THE WITNESS: I've read something along those lines along the way, yes.
Q (By Mr. Thornburgh) And you understand that the mesh devices have a significantly greater surface area than a suture, right?
MR. HUTCHINSON: Object to form.
THE WITNESS: Yeah, in general, sure.
Q (By Mr. Thornburgh) Do you know how many meters of mesh -- of Prolene sutures are knitted and weaved -- or knitted within the TVT device?
A It's a -- I haven't done it. It's a simple calculation, but I don't know. I haven't done it.
Q You're not suggesting that a single suture would have the same tissue response as a much larger piece of mesh, are you?
A I'm just talking about the Prolene resin, the biocompatibility of the Prolene resin. That's all I'm talking about.
Q So are you going to limit your opinions to

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whether or not the TVT device degrades in vivo?
MR. HUTCHINSON: Object to form.
THE WITNESS: I'm not sure I understand your question.
Q (By Mr. Thornburgh) Are you going to limit your opinions at the trial in this case to degradation of polypropylene Prolene material?
A I'm going to limit my opinions to anything that I tell you that's an opinion here today, in addition to whatever is listed as opinions in my report.
Q But not cytotoxicity?
A Correct.
Q And not clinical studies?
A Correct.
Q You talk about a 28-day rat study. That's a short-term study, right?
A It is.
Q And that 28-day rat study should not be extrapolated to determine the long-term safety of the TVT mesh device, correct?
A I think it's one data point amongst many that you'd want to collect.
Q So I don't need to pull out my cytotox

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studies and ask you questions about them?
A You do not.
Q All right. Well, that saved us some time. But leaching is important, right?
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) It's an important issue, right?
MR. HUTCHINSON: Important to what, Counsel?
Q (By Mr. Thornburgh) That you considered in this case?
A What do you mean by "important"?
Q It's important in -- did you look at any documents that discuss leaching of the additives, including the antioxidants?
A Well, I know that they can be extracted in formalin, if that's what you're asking me.
Q Did you look at any studies that showed that the antioxidants actually leach -- bloom and leach out of the TVT device?
A Let's be clear. Blooming and leaching are two separate things, so don't confuse the two.
Q Blooming occurs during the manufacturing process, right?

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A It's been alleged. I've yet to see any definitive data on that, but there's been a few allegations in the documents that blooming has occurred.
Q And leaching occurs over time inside -- in vivo and leaches into the surrounding tissue of the host, right?
MR. HUTCHINSON: Object to form.
THE WITNESS: If you're talking about a mechanism that could be in play or a hypothetical mechanism, yes. If you're defining "leaching," is there any documents that I've reviewed or seen that confirm leaching ever took place in vivo, I have yet to see one document.
Q (By Mr. Thornburgh) You haven't conducted any...
(Discussion off the written record.)
Q (By Mr. Thornburgh) I only have one copy, so I'll just show you. This is the deposition of Dr. Barbolt. You read this, correct?
A Portions of it, yes.
Q Do you understand that he was designated by Ethicon as the person most knowledgeable about this

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subject?
A Yes, I know he's a 30(b)(6) witness.
Q Okay. And you understand that he was working for Ethicon for a number of years, I think two decades, studying Prolene --
A Yeah, I can't --
Q -- in sutures and in mesh devices?
A I can't confirm that number of 20 years off the top of my head, but I understand what you're saying.
Q Okay. So you haven't -- and Ethicon hasn't showed you any of the internal documents regarding -- that showed that the Santanox and the Procol leach out of the mesh, right?
A Not that I recall.
MR. HUTCHINSON: Object to form.
THE WITNESS: Not that I recall.
Q (By Mr. Thornburgh) Right here on page 360 of Dr. Barbolt's January 8th, 2004 deposition, he was asked, "Is it Ethicon's position that the antioxidants in the polypropylene Prolene fibers in TVT can leach from the fiber?"
Answer: "Yes."
Question: "And could you explain to the

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ladies and gentlemen of the jury what we mean by leach?"
Answer: "Leaching means the movement of substances from an implant into the surrounding tissue."
Do you remember reading that deposition?
A I do.
Q And do you have any reason to disagree with Dr. Barbolt?
MR. HUTCHINSON: Object to form.
THE WITNESS: I do.
MR. HUTCHINSON: Hold on just a minute. Object to form. Also object that you haven't shown him the entire document.
THE WITNESS: I do because I --
MR. THORNBURGH: He's read the document.
THE WITNESS: I do because I believe it's based off one study that Mr. Burkley performed. And when I reviewed that data, I was not able to conclude that there was any leaching that took place.
Q (By Mr. Thornburgh) You think this is based off just the one study?
A That's the only document that I could loosely

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connect his testimony to. If there are others, I'd be happy to see, if you have them.
Q You haven't seen the other ones, right?
A No. Do you have some?
Q I'm asking you, you haven't seen any other studies?
A You keep asking me that question --
Q I think I --
A -- and the answer --
MR. HUTCHINSON: Excuse me. One at a time. Dr. MacLean, finish answering the question.
Q (By Mr. Thornburgh) The only one you've seen was the Burkley study, which we'll get to in a minute --
A Sure.
Q -- the 1987 study --
A Uh-huh.
Q -- but you haven't seen any other studies that addressed or looked at leaching or blooming in the TVT Prolene device?
A No, not that I recall.
Q Or the Prolene device, period?
A Correct, same answer.

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Q And if you turn back to Exhibit No. 9, which is the email with -- attached to it is the John Karl memo, it says -- it lists the additives, right, calcium stearate, DLTDP, Santanox R, Procol LA-10, and CPC pigment"?
A Correct.
Q Okay. And it says that the calcium stearate is a lubricant to help reduce tissue drag and promote tissue passage. The DLTDP, it says, is an antioxidants to improve long-term storage of resin and fiber to reduce the potential oxidative reaction with ultraviolet light.
A That's what it says.
Q And is -- have you done any independent work to determine what DLTDP is intended to do in terms of retarding degradation?
A Yeah, we've already talked about it.
Q Okay.
A It's a thioester. It's a secondary antioxidant. It's -- they are designed to be peroxide neutralizing .
Q Oh, so the DLTDP is intended to be peroxide neutralizing, right?
A Correct.

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Q Because this says to protect against ultraviolet light.
A That's true too.
Q And then the Santanox R, an antioxidant to promote stability during compounding and extrusion.
A That's what it says.
Q It doesn't say that there's an antioxidant that is intended to retard oxidative degradation in vivo for -- as a permanent device?
A Correct. And this is not a scientific treatise. This is just a couple of bullet points to describe these antioxidants in general. If you look at the scientific literature, it is crystal clear what those two antioxidants do.
Q And do you see any thioesters? Oh, I think you said earlier that the thioester is the DLTDP?
A Correct.
Q I just want to show you real quick on the same exhibit, it says, "The additive package in use today is the same as was used in the original formulation for years. In addition, in 1991 the Santanox level were reduced slightly by .05 percent." Do you see that?
A I was trying to recall it. I see that.

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Q Okay. So in 1991, according to this document, the primary antioxidant, according to you, was reduced from the Prolene resin, correct?
A That's what it states, which is great because when you look at the dog study -- excuse me. I misspoke.
Q The dog study started before that change?
A It did. It did, correct.
Q So it's not so great, is it?
MR. HUTCHINSON: Object to form. Argumentative.
THE WITNESS: Correct. But I will say that the .05 percent is still within the tolerance that's given for the Santanox R and the DLTDP in the formulation that's given below.
Q (By Mr. Thornburgh) Before you rendered your opinions in this case, did you know that the -- that Ethicon had reduced the primary antioxidant in the Prolene sutures after the seven-year dog study?
A Yes.
Q The less antioxidant you have, the more potential for degradation, right?
A In theory, sure.

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Q Do you think that Santanox R and DLTDP protect the Prolene fibers in the TVT from degradation in pertuity [sic]?
MR. HUTCHINSON: Object to form.
THE WITNESS: Well, let's look at the data. So if you look at the seven-year dog study and you --
Q (By Mr. Thornburgh) Which is before the reduction?
MR. HUTCHINSON: Dan, no. Dr. MacLean -- Dr. MacLean --
THE WITNESS: Yeah, sure.
MR. HUTCHINSON: -- I need you to finish your answer, please.
THE WITNESS: Yeah. If you look at the seven-year dog study, the trend is clear with the physical properties that have been tested. There's no degrading taking place. There's no trend downward in any of that data. So we know that it's lasting for seven years and the trend is positive.
So if you extrapolate a positive trend, that just means that those physical properties continue to get better over time.

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So there's no -- there's no indication that over the decades that this thing may be in a body, that you're going to have physical property reduction like you're -- like you're trying to -- like folks are trying to suggest with this oxidation theory.

Q (By Mr. Thornburgh) The dog study that you're referencing started before Ethicon reduced the Santanox level, right?

A It did, correct.

(Exhibit 10 marked for identification.)

Q (By Mr. Thornburgh) I'm handing you one of the documents that you reference in your expert report as Exhibit No. 10. Have you reviewed this document?

A It looks familiar.

Q It says, "Polypropylene and some polyethylene (PE) resins in their natural state (without additives) are inherently unstable and degrade when exposed to oxygen," right?

A Correct.

Q It says, "The degradation is similar to the rusting (or oxidation) of untreated iron in that the polymers change colors to yellow-brown and begin to flake away until the material becomes useless. When

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polypropylene or PE degrades, chain scission takes place. The physical properties of the polymer deteriorate and its average molecular weight (chain length) decreases, melt flow rate increases and a powdery surface eventually forms." Do you agree with those statements?

A I think that's a good general description of unstabilized polypropylene and polyethylene in the presence of an oxidating environment.

Q It goes on to say in the next paragraph, "Polymer degradation is a natural phenomenon that cannot be totally stopped." Do you agree with that?

A It's a very general statement. I will tell you that, you know, in theory, theoretically speaking, materials can degrade over time. That's -- you know, everything does. Our skin, for example, right, we shed skin over time. Materials degrade over time. That's all that statement is saying. It's -- I don't know how you apply it to a specific polymer or a specific polymer system.

Q I mean, but in your experience, you've dealt with antioxidant additives, right?

A Sure.

Q That are put into polymer resins, not

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necessarily polypropylene, but polymer --

A Right.

Q -- resins, right? And those are put in there to retard or to slow down the degradation process, right?

A Correct.

Q It doesn't stop it completely, does it?

A It depends on the useful life of the device. And all the data that we have right now clearly tells us that none of the properties are trending down. None of the important bulk physical properties of the Prolene, none of the important bulk physical properties of the mesh are trending down.

(Exhibit 11 marked for identification.)

Q (By Mr. Thornburgh) I'm handing you what's been marked as Exhibit No. 11. This is an internal Ethicon memo dated September 30th, 1987, right?

A It is.

Q And it says that -- "IR microscopy of explanted Prolene received from Professor Guidon," right?

A Correct.

Q And this was 1987. This was like a long time ago --

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A It's --

Q -- several decades ago?

A It was about 28 years ago.

Q Twenty-eight years ago. And do you know who Dr. Guidoin is?

A Only from what I've read in the files.

Q It says, "Samples of Prolene suture carefully removed from human" -- let me ask you this question: Have you -- have you reviewed any publications by Dr. Guidoin, peer-reviewed publications?

A I don't recall.

Q "Samples of Prolene sutures carefully removed from human vascular graft explants received from Professor Guidoin were examined by IR microscopy as is. A Prolene suture control was examined for comparison."

It goes on to talk about how there were -- in the two-year explant, there were no cracks, and in the eight-year explant, there was severe cracking, right?

A Correct. That's what it says.

Q It says, "Some samples of the eight-year were examined optically. Using a needle, the scratched [sic] surfaces were easily wiped off and deposited on a KBr window. The surface scrapings had the handling and consistency of a waxy snow. The sample was not

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conducive to IR microscopy in this form however. Similar treatment with needles on sterile packaged Prolene and the two-year sample generated no scrapings."

So there were some changes, right, surface changes on this explant that were consistent with a waxy snow?

A I wouldn't -- I wouldn't characterize them as surface changes, but there was a waxy snow material found on the exterior of the implant.

Q And we just looked at the document and you agreed that degraded polypropylene becomes powdery, correct?

MR. HUTCHINSON: Object to form.

THE WITNESS: Right. I didn't say waxy.

Q (By Mr. Thornburgh) "The surface scrapings spectra are very different from the bulk spectra, and both types of spectra showed no evidence of the presence of protein," right? Do you see that?

A Yes.

Q "The surface scrapings spectra of the eight-year clearly indicated polypropylene."

So they scraped it off, right, the stuff

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scraped off, they tested it using IR microscopy, and it -- and what they scraped off was polypropylene?

MR. HUTCHINSON: Object to form. Compound.

Q (By Mr. Thornburgh) Right?

MR. HUTCHINSON: Compound question.

THE WITNESS: That's what it says.

Q (By Mr. Thornburgh) And just above that, the first paragraph on the second page of the Exhibit 11, it says, "The surface scrapings were melted at 147 to 156 degrees Celsius on the Mettler hot stage. This is the melting range previously observed for oxidatively degraded polypropylene," right?

A That's what it states.

Q And you disagree with that, don't you?

A I do.

Q The conclusions that were drawn by Dr. Burkley, who was an Ethicon employee -- you understand that, right --

A I do.

Q -- an Ethicon scientist, right --

A He was.

Q -- and worked for Ethicon for many, many years, you've seen -- you've numerous documents with

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his name on them, right?

A Not at this time. Not at this time. He has just joined the company at this time. We're talking about Dr. -- or Mr. Burkley?

Q He's worked -- he's an employee that has been with Ethicon for a number of years?

A Presently. Not in 1987.

Q Okay. Okay. So you don't think he was qualified to render these conclusions?

A I didn't say that. I was just clarifying when he was employed and how much experience he had and --

Q Do you know what his position was there?

A Not specifically. He looks like he's working at the direction of other senior scientists.

Q He's testing degraded polypropylene 28 years before any of this litigation ever started, right?

MR. HUTCHINSON: Object to form.

THE WITNESS: Correct.

Q (By Mr. Thornburgh) And outside of the courtroom, when he's in his lab working for Ethicon when there's no litigation going on, he writes that "The amount of DLTDP is reduced in the explanted sutures. No DLTDP is observed in the surface scraped

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(cracked regions) of the eight-year explant. The observed DLTDP decreases with implant time."

In other words, it's leaching out over time, according to Dr. Burkley, right?

MR. HUTCHINSON: Object to form. It's also an argumentative question, Counsel.

THE WITNESS: That's what it states, but that's not what the data is telling us. And you cannot use FTIR as a quantitative tool. It's just not -- just not how it works unless you do a significant amount of studies.

Q (By Mr. Thornburgh) Dr. Burkley --

A I understand.

Q -- scientist for Ethicon, is saying --

A Sure.

Q -- DLTDP is leaching out over time, right?

MR. HUTCHINSON: Object to form.

THE WITNESS: That's what --

MR. HUTCHINSON: Mischaracterization of the document. Dr. MacLean, go ahead.

THE WITNESS: That's what Item No. 1 in the conclusions say. I'm telling you that he did not arrive at that conclusion in a scientific manner.

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Q (By Mr. Thornburgh) He goes on to say, "No protein is observed in any spectra of the explanted sutures," right?
A That's what he says.
Q "The surface scraped material from the cracked regions of the eight-year explant has a melting range indicative of degraded polypropylene. The IR spectra of this scraped material is clearly polypropylene." Did I read that correctly?
A That's what it says.
Q And so you disagree with Dr. Burkley, right?
A I do.
Q So you disagree with Dr. Wood so far. You disagree with --
A No, no, no. I didn't say I disagree with Dr. Wood the way you're phrasing it. I was saying that there's a second mechanism that they did not address.
Q You disagree with Dr. Wood's definitive conclusion?
A That's correct.
Q You disagree with Dr. Thames, an expert in this case for the defendants?
MR. HUTCHINSON: Object to form.
THE WITNESS: It's --

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MR. HUTCHINSON: Hey, wait a minute. Object to form. Mischaracterizes the testimony.
Q (By Mr. Thornburgh) Right?
A It's the same answer I just gave you for Wood.
Q You disagree with Dr. Barbolt, right?
MR. HUTCHINSON: Same objections.
Q (By Mr. Thornburgh) Right?
A I -- not the way you're phrasing it, no.
Q Do you agree with Dr. Barbolt that the surface layer of the TVT Prolene device degrades in vivo, that the TVT device undergoes surface degradation?
MR. HUTCHINSON: Object --
Q (By Mr. Thornburgh) Do you agree or disagree with Dr. Barbolt?
MR. HUTCHINSON: Object to form.
THE WITNESS: I thought you were talking about the leaching with Dr. Barbolt.
MR. THORNBURGH: Well, that's one issue, but he had --
MR. HUTCHINSON: Hey, guys, hey, look, I'm not going to say it again; both of you

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don't need to talk over each other. Let Dr. MacLean finish his answer, if you remember the question.
THE WITNESS: I need to hear the question again.
Q (By Mr. Thornburgh) Dr. Barbolt testified that the TVT device undergoes surface degradation, that the surface cracks and peels away from the surface. Do you disagree with Ethicon's scientist, Dr. Barbolt, who is speaking on behalf of Ethicon as the 30(b)(6) witness, that the Prolene in the TVT degrades, surface -- undergoes surface degradation?
MR. HUTCHINSON: Object to form. Mischaracterizes the testimony of Dr. Barbolt.
THE WITNESS: I disagree with that.
MR. HUTCHINSON: Dan, we've been going for about an hour. Let me know when we're at a good spot to take a break.
MR. THORNBURGH: Let me finish this line of questioning --
MR. HUTCHINSON: Okay.
MR. THORNBURGH: -- and then we'll take a break.

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Q (By Mr. Thornburgh) Dr. Barbolt's January 8th, 2014 deposition, page 409, lines 2 through 13.
MR. HUTCHINSON: Counsel, do you have a copy for me or the witness? Counsel, do you have a copy for me or the witness?
MR. THORNBURGH: No.
Q (By Mr. Thornburgh) 409, line 2, question: "And that's Ethicon's position, as a spokesperson for Ethicon, it's Ethicon's position that degradation, surface degradation, can occur, correct?"
The witness answers, "Yes."
"And this was well known in advance of this statement that the material is not absorbed, nor is it subject to degradation, correct?"
"Yes. This was from 1992."
Do you disagree with Dr. Barbolt, who is an Ethicon employee, an internal scientist, who was designated by Ethicon as the person most knowledgeable about degradation, a 30(b)(6) witness, who testified that the Prolene in the TVT undergoes surface degradation?
A I do.
MR. HUTCHINSON: Same objections.

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THE WITNESS: I do. I disagree.
Q (By Mr. Thornburgh) And you understand that Dr. Barbolt -- this is 2014 -- Dr. Barbolt had been working with the company for a couple decades?
A That's what it says.
Q And he was the person who was there in the lab working with Prolene sutures and Prolene mesh devices, right?
A Apparently.
Q And you didn't form an opinion about TVT or Prolene until after you were retained by Ethicon in this case, correct?
MR. HUTCHINSON: Object to form.
THE WITNESS: That's correct.
Q (By Mr. Thornburgh) And in addition to disagreeing with Dr. Barbolt, you also disagree with Dr. Burkley?
A On this document, I do, absolutely.
Q From his study from 1987, right?
A Correct.
MR. THORNBURGH: Want to take a break?
MR. HUTCHINSON: Yeah. Not long.
THE VIDEOGRAPHER: We are now going off the video record. The time is currently

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2:44 p.m. This is the end of Tape No. 3.
(Recess taken.)
THE VIDEOGRAPHER: We are now back on the video record with Tape No. 4. The time is currently 2:59 p.m.
(Exhibit 12 marked for identification.)
Q (By Mr. Thornburgh) Doctor, I'm handing you what's been marked as Exhibit No. 12. Before we went on the break, we were talking about some of the internal documents that were done by Ethicon. And around the same time period, there were other researchers outside of Ethicon who were also analyzing Prolene for degradation, right?
A I believe so.
Q In fact, Dr. Jongebloed -- I'm not sure if I pronounced his name right; it's J-O-N-G-E-B-L-O-E-D -- published an article called the "Mechanical and biomechanical effects of man-made fibres and metals in the human eye, a SEM-study," in 1986. Do you recognize this study? Have you seen this study before?
A I have.
Q And in this study, Jongebloed and his colleagues analyzed explanted sutures, including Prolene, correct, from human eyes?

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A They did, correct.
Q And it says, "The biocompatibility of these materials has been the subject of investigation of several authors," and they list some authors.
So there were other authors back in the '80s who were also looking at Prolene degradation. And Jongebloed and his colleagues go on to write that, "Nevertheless, there is still no clear explanation of the phenomenon one can observe in the pictures, although there are strong indications for enzymatic reaction [sic] being the cause of the surface changes on these materials." Did I read that correctly?
MR. HUTCHINSON: Object to form.
MR. THORNBURGH: I'm on the first page of Exhibit 12.
THE WITNESS: And I'm just trying to track on which paragraph you just read.
Q (By Mr. Thornburgh) Second -- see the introduction?
A Yep.
Q See where they say that they looked at Prolene and other sutures that were explanted from the human eye?
A Correct.

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Q And they say -- he goes on to say, "There is no clear explanation of the phenomenon one can observe in these pictures, although there are strong indications of enzymatic action being the cause of the surface changes on these materials."
So he's just giving a history of sort of what the theory back then was in 1987, right?
MR. HUTCHINSON: Object to form.
MR. THORNBURGH: 1986 --
THE WITNESS: That's what he states.
MR. THORNBURGH: -- right?
Q (By Mr. Thornburgh) But then he says, you know, as a good scientist does, he goes on and says, "On the other hand, all kinds of explanations are given, such as fixation or drying artifact, mechanical damage when the lens and loops are taken out of the eye, damage caused by the irradiation in the SEM, possible effects of the sterilization agents, UV light, et cetera."
All right, so he's saying maybe there's another cause, maybe it's not oxidative degradation that's occurring inside these human eyes of these Prolene sutures, maybe there's another cause, so let's test it.

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MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) Right?
A He doesn't -- he does not postulate oxidation/degradation. He just says enzymatic action.
Q What else would the enzymatic action be?
A Could just mean proteins that are actually bonding onto the surface.
Q Have you read this?
A I've read -- I'm just telling you what -- you just asked about a specific passage in the introduction, and I'm just -- I'm just reflecting on it.
Q Well, if you've read it, you know that he goes on to talk about free radicals and the inflammatory response and oxidative degradation.
A Correct. But that's not what you had just cited to me.
Q Well, okay. "Materials and Methods." The Prolene material was part of an open J-lens, and it was implanted in a Pakistani patient for one year, right?
A Correct.
Q See the "Results" section? And it was explanted apparently because the patient was having

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complications, right?
A I believe that's what it says, correct.
Q So both Prolene loops showed severe degradation of the surface layer. And they show some pictures. Figure 1, they say, "The irregular cracks in this deposit (see arrows) are due to drying, a common phenomenon in SEM specimens of inhomogeneous structure. Figure 2 shows at high magnification the very regular pattern of striations. Some parts of the surface are crossed [sic] with a thin deposit, comparable to the layer seen in Figure 1. The degradation of the surface layer can be observed in more detail in Figure 3. Part of the surface layer is detached, exposing the subsurface layer, which shows a similar cracking pattern (see arrows)."
He goes on to write, "The fact that the subsurface layer shows a similar cracking pattern of degradation is a clear indication of biodegradation. If the phenomenon we observe were the result of the drying of a deposit, then the cracks in it would have a much more regular" -- "irregular character, like the cracks seen in Figure 1."
The total diameter of the degraded loop has certainly not increased, right? So you would expect

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that if it's protein that's forming around the surface of the diameter of the fiber, that the diameter would increase, right?
MR. HUTCHINSON: Object to form.
THE WITNESS: Where do you see his diametrical measurements? I know where the statement comes from. Where are the diametrical measurements that he's referring to?
Q (By Mr. Thornburgh) Are you saying because they're not there, you don't believe him?
MR. HUTCHINSON: Objection. Counsel, that's argumentative. Don't do that with this witness.
MR. THORNBURGH: I'm just trying to understand if that's what his point is.
MR. HUTCHINSON: Okay. Well, you can ask -- you can ask it that way, but don't --
Q (By Mr. Thornburgh) Is that -- is that the --
MR. HUTCHINSON: Hey, Dan, you can ask it that way, but don't argue with the witness.
Q (By Mr. Thornburgh) Is the position that

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you're taking, that this study in 1986 isn't a study that can be relied upon, because you don't see diametric measurements?
A Yes. He's making a bold statement about the thickness of the cracked layer with respect to the original diameter of the fiber, and I would expect that data to be in here, yes. That would be scientifically sound to put that in there. You're talking about a cracked layer that is on the order of a micron. You're talking about a fiber diameter that's on the order of 100 to 150 microns. So, yes, you need to show that specific measurement to make that statement.
Q Did you make any of those measurements? Have you ever done that analysis?
A I've seen other folks try to attempt it, yes.
Q Have you done it?
A I have not done it.
Q If you look at the --
A But I will tell you it can be done. I mean, you can make these discrete measurements. I don't know if even if you make them, if you can make that connection; but if you're going to make that statement, you better have the data to support it.
Q We're talking about Prolene here, right?

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A We are.
Q The same material in the TVT devices, right?
A Correct.
Q And if you look at Figure 1 through 4 of the SEMs, that's some significant cracking, right?
MR. HUTCHINSON: Object to form.
THE WITNESS: I'd say it looks typical cracking from what we've seen over and over and over again for the last 20 years of documents.
Q (By Mr. Thornburgh) It is -- it is typical because what happens when you -- when you purposely degrade it using UV radiation, the TVT mesh that you analyzed, it looked very similar to this, didn't it?
MR. HUTCHINSON: Object to form.
THE WITNESS: No, it didn't. Let's put them side by side.
MR. THORNBURGH: We'll do that in a moment.
THE WITNESS: Sure.
Q (By Mr. Thornburgh) So you think that your cracks look different than the cracks that we're seeing in all these publication for the last 20, 30 years?
MR. HUTCHINSON: Object to form. It's

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argumentative, mischaracterizes what the witness just told you.
THE WITNESS: They certainly don't look like this -- I'll call these concentric or repetitive striation cracks that you see in the top right-hand corner on Figure 2.
Q (By Mr. Thornburgh) What about Figure 3?
A Maybe, maybe some similarities, but...
Q And Figure 3 is the figure that was described here as, "The degradation of the surface layer can be observed in more detail in Figure 3."
A You cannot make an assessment of whether you have degraded polypropylene just by looking at SEM images, period.
Q Not only the top layer is cracked, but also the layer that's underneath the top layer.
A Okay. Show me where he's characterized those materials. Where is the chemical composition of those cracks?
Q If you go to page 311, it says, "The phenomenon observed on the surface of implanted Prolene is a topic of interest to several authors, as already noted. The Prolene we investigated had remained in the eye of a Pakistani patient for one year and showed

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severe changes on the surface of both. Nonimplanted material given the same treatment did not show any surface changes when examined in SEM. Nonimplanted material soaked in distilled water for a long time, dried in air, sputter-coated with gold and examined in the SEM under the same conditions, did not show any surface changes either. We think the surface changes observed in the implanted Prolene are the result of biodegradation by enzymatic action of the tissue fluids."
You disagree with this scientist, as well, from 1986, right?
A I do because he's not shown us what the chemical composition is, and that's the only way you can determine, A, if that cracked layer is polypropylene -- or Prolene, rather; and B, if it's degraded. He hasn't done any of that in this study.
Q But if he showed you a chemical composition, if he did an FTIR and reported it in this study, you'd say, "But there's protein surrounding that fiber," right?
MR. HUTCHINSON: Object to form.
THE WITNESS: If there were protein surrounding it, I would, yes.

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Q (By Mr. Thornburgh) So under your way of thinking, it's impossible to determine whether or not an explanted TVT Prolene device degraded in vivo?
MR. HUTCHINSON: Object to form. Mischaracterizes the witness's testimony, Counsel.
THE WITNESS: If you look at our staining study, I think it's conclusive. The staining study tells you, when you combine it with what Dr. Iakovlev has done, that this cracked layer is not oxidized Prolene.
Q (By Mr. Thornburgh) You degraded it through UV radiation and it cracked, right?
A It didn't stain.
Q Well, we're going to get to that in a moment. So you disagree with another set of authors from 1986? Jongebloed, right?
MR. HUTCHINSON: Object to form. Dan, that mischaracterizes the testimony.
Q (By Mr. Thornburgh) You disagree with their conclusion without more data that the -- that the explanted sutures were degraded?
A If you're going to -- if you're going to --
MR. HUTCHINSON: Hold on just a minute.

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Object to form.
THE WITNESS: If you're going to state that a polymer is degraded, you should have molecular weight data that supports that opinion, and he does not. The very definition of degradation is not visual cracks on a photograph or a micrograph, which that is the mistake that researcher after researcher after researcher mistake -- that's the mistakes that they made.
You need molecular weight data to confirm the true degradation, polymer chain scission. I've broken chains down, I've degraded. That's the definition of "polymer degradation." I need that data. You can't do it through FTIR, you can't do it through just -- through these micrographs that you keep showing me.
Q (By Mr. Thornburgh) You can do it through melting point?
A No, you can't.
Q The melt -- if there's a --
A I just explained to you --
MR. HUTCHINSON: Hey, Dan, stop it.

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MR. THORNBURGH: I'm --
MR. HUTCHINSON: No, stop it. No.
MR. THORNBURGH: Go ahead.
MR. HUTCHINSON: I want you to finish your answer, and then Dan Thornburgh can ask another question.
THE WITNESS: Okay.
MR. HUTCHINSON: But I need you to finish your answer right now.
THE WITNESS: Okay. My answer is: With regard to melting point, I am telling you it is a scientific fact when polypropylene will be plasticized or with any polymer plasticized, you will reduce its melting temperature. And we know these materials are plasticized in vivo. That is also a scientific fact based on Jordi's work.
Q (By Mr. Thornburgh) So hold on. I want to understand your opinion.
A Sure.
Q Okay. You would agree with me that if you have a -- if you were to take a neat polypropylene, not explanted from the human body, no protein, not in a biological environment, and you degraded it,

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oxidatively degraded it, the -- and then you melted it and the melt point was lower than the pristine implant, that melt point change is evidence of oxidative degradation, right, number one?
A It can be.
MR. HUTCHINSON: Object.
Q (By Mr. Thornburgh) And, number two, when you have a decrease in the melt point, that corresponds with a drop in the molecular weight?
A No, not for the reasons I just told you. I can get a suppression of melt temperature without reducing molecular weight. That is a fundamental tenet that everyone seems to just dismiss. You don't need to have a reduction or a degradation of the polymer just to see lower melt temperatures. I can plasticize the material and still get there. And we know the material is being plasticized based on the seven-year dog study data.
Q Maybe you didn't understand my question.
A I think I did.
Q My question was: If you took a neat Prolene suture or mesh and you intentionally oxidized it without it ever being in the biological environment --
A Yep.

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Q -- and it -- the surface cracks and you do FTIR and it shows 1740, and then you do melt point and the melt point has dropped, that's evidence of oxidative degradation, number one, right?
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) All those things, right?
MR. HUTCHINSON: Object to form.
THE WITNESS: In that hypothetical situation, in the absence of in vivo environment, that's all reasonable.
Q (By Mr. Thornburgh) And in the same hypothetical situation, then you do a melt point test, thermal analysis, you melt it, the melt point is lower than the pristine sample, that's also evidence of oxidative degradation and it's evidence of a corresponding drop in molecular weight?
MR. HUTCHINSON: Objection, compound.
THE WITNESS: I would say implicitly, yes, but you would want to make the molecular weight analysis. But, again, you've excluded the in vivo conditions, which are very, very much in play here.
And we know the material is not degrading. The molecular weight analysis

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tells us that. The tensile data from the seven-year dog study tells us that. There's no hard scientific data that says these Prolene materials are degrading in vivo via oxidation, or any other mechanism, for that matter. These materials are plasticizing, they're becoming tougher, they're improving their flexibility and ductility over time. It's irrefutable. That data is irrefutable.

Q (By Mr. Thornburgh) In your expert report, Exhibit No. 2, you have a section called "Formaldehyde-Protein Crosslinking," right?

A I do.

Q I'm just trying to understand your opinion. So is it your opinion that the cracked layer that we're seeing on the outside of the TVT Prolene fibers in a -- in a specimen that was explanted and then put in formalin and then reagents were used to dissolve the tissue, that those cracks were actually from the formaldehyde-protein crosslinking and not from degraded polypropylene?

A Let's just start with do I think that they're from the crosslinked formaldehyde-protein polymer that

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we know is forming in the storage, and the answer to that question is yes. If I put a brittle layer, a brittle crosslinked polymer on the outside of these fibers, take it out of the formalin and then dehydrate it in the environment, like we've seen Ethicon do, and they've seen cracks actually appear under those conditions, then yes, the answer is yes, that brittle layer can form cracks under the right environment.

Q Is that a different opinion than you have regarding -- I can't speak -- plasticization?

A I don't know if it's different. I would just say it's an additional opinion that I have.

Q What are the distinctions between plasticization and crosslinked formaldehyde-protein bond?

A Okay. So let's start with plasticization. So that is the diffusion of small molecules into the fibers and filaments that actually cause the material to experience changes in its physical properties; and in this case, the net effect is all positive, where you have increase in ductility, you have increase in toughness, you have increase in flexibility. That is exactly what the dog study tells us.

So I'm just saying that -- and by the way,

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those molecules that are diffusing in have carbonyl groups in them. So if I go up to ATR or an IR instrument and I place an in vivo specimen or specimen that was once in vivo and I try to sample it and I get a carbonyl peak, I don't -- that doesn't surprise me because there are carbonyl functionality groups in those molecules that are now inside the fiber. So that's the answer to your first question.

Q All right.

A Do you want to ask me the second --

Q Are you done?

A I think I'm done.

Q All right. So for a crosslinked formaldehyde --

A Okay.

Q -- if you -- do you agree -- well, let me ask you one for the first question. How long does it take for the crosslinking to occur once the explant is exposed to formalin?

A Well, it would -- it would start right away, and there's probably some relationship where -- as a function of time, it asymptotes or reaches a point of diminishing return where you actually react it as much as you can based on the available formaldehyde and the

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available amount of protein. But that reaction would start right away. But the degree of crosslinking, the amount of crosslinking, that would be a function of time.

Q And are you aware of some testing that was conducted by Ethicon to determine whether or not the fixative material had some sort of impact on causing the cracking on the surface layer?

A Yes. I think they did some short-term maybe -- serum dips with formalin testing. I'm just going off memory.

MR. THORNBURGH: I'm going to have marked as Exhibit No. 13 a memo dated November 13th, 1984.

(Exhibit 13 marked for identification.)

Q (By Mr. Thornburgh) This is another internal document from Ethicon, right?

A It is.

Q And the subject line is "Fourier transform-infrared examination of Prolene microcrack and photooxidized polypropylene," right?

A Yes.

Q Do you see that?

A I do.

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Q And do you recognize this memo?
A I do.
Q And do you understand that in this memo, the Ethicon scientists were continuing to analyze the microcracking that was being observed on their Prolene sutures?
A Correct.
Q And this memo was put together to investigate the microcracked Prolene material by three methods of infrared examination, and the question that these IR examinations try to answer is what is the composition of the exterior cracked surface of the explanted Prolene sutures.
In the course of examining the explants, the second question addressed is: Do current methods of treating the explants (formalin storage and soluene treatment to remove protein) produce artifacts in the IR results? And that's what you were talking about, right? You're talking about soluene or formalin having a chemical reaction that produces an artifact on the IR, right?
MR. HUTCHINSON: Object to form.
THE WITNESS: I'm not quite sure what you're asking, if you could just do that

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again.
Q (By Mr. Thornburgh) Well, this is -- this is what your -- you hypothesized --
A It's not a hypothesis.
Q -- is a -- is work that was done by Ethicon in 1984 to determine whether or not IR examinations can determine what is the composition of the exterior cracked surface of explanted Prolene sutures, and whether or not there's an impact of treating the samples with formalin storage and soluene treatment, right?
A Okay. That's what it says, yes.
Q And that's what you have theorized in this case?
A I have just theorized that once you go into formalin, you have to be very careful. All of the data becomes suspect, and I'll tell you why. When you put -- when you put the specimen in formalin, there are chemical and physical reactions that are taking place that are beyond whatever might have taken place in vivo.
For example, we know that you can extract out the antioxidants. Dr. Jordi has proven that to us. And we know that there's a chemical reaction going on,

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there's actually polymerization, crosslinking going on. You're physically creating another material that's crosslinked that wasn't there in vivo. There's no denying that protein plus formaldehyde will polymerize. And then there's also moisture uptake and dehydration when the sample goes in and when the sample goes out.
So everything that's happening in formalin is so after the fact that you have to look at this data very, very carefully. That's what I'm -- that's one of the points that I'm making.
Q Do you agree with me that that's one of the -- the question that Ethicon scientists were trying to answer when they conducted these studies on November 13th, 1984?
A I think that they were just looking at the ability to clean with soluene and -- let me just read this before I make any more comments.
I would say they're trying to determine -- just like it says here, they're trying to determine the composition of the exterior cracked surface of the explanted Prolene. I think that's what they're investigating.
Q They're trying to determine whether or not the methods of treating the explants, formalin storage

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and soluene treatment, to remove protein produce artifact in the IR results, which is what you've been stating or opining about in this case?
A What artifacts are you referring to?
Q A protein-formaldehyde bond, for example.
A Correct.
Q That would be an artifact, right, on the IR?
A Right.
Q And so that's what they're trying to answer, right?
A Yes. And we see it in the spectrum; we see proteins in some of these spectra. I mean, is that what we're debating, whether there's actually --
Q No, so let's go -- let's see what the deal is, okay?
A Okay.
Q Let's read it. And see how the surface pieces of -- the second paragraph on page 2 of Exhibit 15 [sic], the 1984 internal Ethicon document, says, "Pieces of protein were visually observed to adhere to the explant surface. A set of experiments was done to remove protein from Explants 84-194 and the serum coated 5-0 virgin Prolene, and using" -- "and 2 using soluene. The explant and suture were then examined by

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ATR and microscopy to see if the cracked surface was removed and to determine the surface composition. The ATR spectra show that protein was efficiently removed from the surface of both explant and protein coated virgin Prolene using soluene. No spectral evidence of soluene was observed, indicating that this solvent washed away cleanly with water. Microscopic examination revealed that the cracks remained." Right?

MR. HUTCHINSON: Let the record reflect this is Exhibit 13 and not 15.

MR. THORNBURGH: Exhibit 13.

THE WITNESS: Correct. And let me -- okay.

Q (By Mr. Thornburgh) If you go just above that, it will help answer the question, "What are we talking about here," right? So to determine the -- on page 1, bottom paragraph, "To determine the relative sensitivity of ATR for observing protein, normal production lot Prolene was coated with serum protein. 1918-34-1 was dipped for 10 seconds and 1918-34-2 was dipped for 10 minutes. Both sets were dried and examined by ATR and also microscopically by Dr. Matlaga. The spectra clearly showed very strong protein bands along with polypropylene. Figure 6 also

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shows a 1730 band which is in the region of oxidized polypropylene. The origin of the band is not understood in this" -- "is not understood in this sample. It does appear, however, in the transmission spectra of serum protein as deposited on NaCl as shown in Figures 3 and 4 and therefore may be related to protein. The coatings were found to be nonuniform and the apparent thickness of the areas that were coated varied between 2 and 4 microns. The ATR surface now appeared to be quite sensitive to protein present on the surface of the suture.

"Since pieces of the protein were visually observed to adhere to the explant surface, a set of experiments was done to remove protein from explant 1894 [sic] and the serum coated 5-0 virgin Prolene and 2 using soluene. The explant and suture were examined by ATR and microscopy to see if the cracked surface was removed and to determine the surface composition. The ATR spectra obtained show that protein was efficiently removed from the surface and both explant and protein coated virgin Prolene suture" -- "coated virgin Prolene using soluene. Microscopic examination revealed the cracks remained.

"To obtain insight into the composition of

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the cracked surface, pieces of the explant and pieces of the soluene treated sample were prepared and sent to McCrone Associates for analysis using FTIR. Dr. McDivitt and Burkley also brought these samples to Digilab to have them examined on their micro/IR system. The explant pieces were examined and transmission IR spectra are described in detail below."

So then we have the IR here, right? "The explant flake, not soluene treated - The transmission IR spectrum showed strong protein bands with normal polypropylene bands as expected. The amide band" -- "the amide band at 1760 [sic] was suspiciously broad and might be hiding oxidation bands if present at 1720," right?

A Yep.

MR. HUTCHINSON: Form.

Q (By Mr. Thornburgh) So this is what -- this is what you're talking about, right?

MR. HUTCHINSON: Same objection.

THE WITNESS: This is not necessarily what I'm talking about. I'm just working through the study with you, so --

Q (By Mr. Thornburgh) Okay. The protein bands in the -- so Figure 10 shows the Explant 84-194

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flake after soluene treatment of the suture. "The protein bands in the transmission spectrum are significantly smaller relative to untreated explant spectra. A shouldering band at 1720 is more clearly visible, indicating possible ketone species."

Ketone species would be a carbonyl group, right?

A They would. They would contain carbonyl.

Q Okay. And then the explant "melted/yellow cap" -- so here we have, "While soluene removes surface protein effectively from microcracked sutures as monitored by ATR, it apparently is not removing protein that has penetrated below the surface of the flakes." That's what you're talking about, right?

MR. HUTCHINSON: Object to form.

THE WITNESS: I'm not -- no, I'm not convinced that that's what I'm talking about, but keep reading.

Q (By Mr. Thornburgh) "And is observed by transmission IR. Thus the cracked surface layer appears to be composed of a protein surface beneath which lies oxidized polypropylene penetrated or plasticized by protein."

This is what you're -- this is your theory,

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right?
MR. HUTCHINSON: Object to form.
THE WITNESS: That's not my theory. I just need a minute. I want to regroup on my thinking on this document.
Q (By Mr. Thornburgh) They're testing your theory out?
MR. HUTCHINSON: Counsel.
THE WITNESS: Okay, so my --
Q (By Mr. Thornburgh) Okay. So they do a number of studies to see if protein is getting trapped underneath, if formaldehyde is reacting with the protein creating some sort of FTIR or IR artifact. And they conclude after they run all these different studies that you've just reviewed -- you see right here, it says -- very top of page 4, ETH.MESH.15958339, "The series of polypropylene film experiments were done to: Characterize oxidized polypropylene; characterize protein on polypropylene; verify that formalin does not react or alter the polypropylene explants; determine if soluene removed protein efficiently and washed away cleanly; determine if soluene causes chemical change to the explants; compare experimentally prepared films to the explants."

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That's what we're talking about, right? That's a study that you'd want to know and you'd want to consider when formulating your opinions in this case that what we're seeing on IR spectra and all of these studies is something other than oxidation?
MR. HUTCHINSON: Object -- hold on just a minute. Object to form. Dan, I'm not real sure what your question was. It was -- in all honesty, it was multiple questions.
MR. THORNBURGH: Okay.
MR. HUTCHINSON: So what is the --
Q (By Mr. Thornburgh) The purpose of the --
MR. HUTCHINSON: -- what is the question?
Q (By Mr. Thornburgh) The purpose of this study was to test the theory that you've offered in this case?
A Okay, fine. Let's go -- let's go through --
MR. HUTCHINSON: Object to form.
A -- let's go through 1 through 6 and see if we can get on the same page.
Q Okay.
A All right.
Q Characterize -- so you want to go through 1

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through 6? We just did. I thought we'd --
A No, you did.
Q -- go into the results.
A You did.
Q Why don't we go to the results?
A I'd like to go through 1 through 6 first.
Q Okay. The purpose of the study was to characterize oxidized polypropylene, right?
A Fine, let's stop there. So first of all, this is polypropylene film, not Prolene. And all they've done in No. 1 is they've oxidized polypropylene. Okay, fine.
Q The second was to characterize protein on polypropylene. That's something that you --
A Sure, let me --
Q This is something --
A Right.
Q -- this is data points that you'd want to consider, right?
MR. HUTCHINSON: Okay, guys, one at a -- one at a time.
THE WITNESS: Yes, I want to consider it, and I have considered it. We know for a fact that protein is on the Prolene mesh when

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it comes out of the body. We know that.
Q (By Mr. Thornburgh) The No. 3 purpose of the study was to verify that formalin does not react or alter the Prolene [sic] explants. It's a good data point to have, right?
MR. HUTCHINSON: Object. Mischaracterizes the document.
THE WITNESS: Correct, it does mischaracterize the document. All they've done here is they've dipped it in --
Q (By Mr. Thornburgh) The purpose of the study -- I'm just --
MR. HUTCHINSON: No, I'm sorry.
Q -- reading of the study.
MR. HUTCHINSON: Dan, stop. I'm telling you to stop. Dr. MacLean --
MR. THORNBURGH: No. Hold on. Hold on. No, you know what, Chad --
MR. HUTCHINSON: -- you can finish your answer.
MR. THORNBURGH: You know what, Chad, my question was, the No. 4 purpose that's listed here was to determine if soluene removed protein efficiently and washed away

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cleanly.
MR. HUTCHINSON: You can -- you can read the transcript. That wasn't your question.
MR. THORNBURGH: Okay. My question was to verify --
MR. HUTCHINSON: But my point --
MR. THORNBURGH: -- that formalin does not react or alter the polypropylene explants.
MR. HUTCHINSON: My point is to let Dr. MacLean finish answer your question, then ask another one.
MR. THORNBURGH: He's not answering my question.
THE WITNESS: I'm trying to.
MR. THORNBURGH: You're not.
Q (By Mr. Thornburgh) My question is: One of the studies that are identified in 1 through 6 here was to verify that formalin does not react or alter the polypropylene explants. That's what it says, right?
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) Did I read it accurately?
A You did. But we're not talking about the

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polypropylene explants. I'm talking about the tissue that's sitting on top of the polypropylene explants.
Q That's what they're talking about, that's --
A Yes, for a study that --
MR. HUTCHINSON: Hey, Dan, hey, look, I'm going to stop this deposition if you guys keep on talking over each other.
MR. THORNBURGH: I'm just trying --
MR. HUTCHINSON: The witness is entitled to finish answering his question, and please let him do that.
THE WITNESS: Ten seconds and ten minutes dipped is not the same as being in an in vivo environment for months, if not years, period. So you can't extrapolate these. And I don't disagree with this statement that they're saying, by the way, that the formalin in this study is not interacting with the polypropylene explants.
I'm telling you that the -- it is a -- it is a fundamental fact of formalin fixation that when I take a tissue with protein obviously in it and I put it in formalin, it fixes, it crosslinks. That's all. Does

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it -- is it affecting the polypropylene itself, the explants? This data tells us not, and I have no reason not to believe it, and I think it's some irrelevant.
Q (By Mr. Thornburgh) So far I'm -- all I've done so far is read to you the purposes. We haven't even looked at the conclusions yet.
A Right. Fine. But I'm telling you those purposes are fairly innocuous and irrelevant to what we're trying -- what the heart of the matter is.
Q The other -- the other purpose, No. 5, was to determine if soluene causes chemical change to the explants; and No. 6 was to compare experimentally prepared film to the explants.
A Okay.
Q Did I read all that correctly?
A You did. Let's -- can we just talk about 5? Because I don't think we're on the same page with soluene. Do you know what -- do you know what soluene is?
Q It's a fixative.
A It is not a fixative. It is a solution to clean tissue. The fixative here is -- is formalin.
Q Formalin, right. They used soluene to clean

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the tissue that was --
A Correct.
Q -- preserved in formalin?
A Correct.
Q Yeah, so I --
A It's okay.
Q -- I misstated it.
A That's okay. I want to make sure we understood what that -- what that was telling us.
Q Which is -- which is an important data point to consider, right?
A Sure, it tells us the soluene is not negatively interacting with the explant in this specific short-term study. And I will tell you that the statement where it says that soluene effectively cleans is false. If you look at the FTIR data on page ending in 346 for Bates number, it's Figure 7, there are clearly, in my opinion, protein peaks. They are subtle, but there are protein peaks here, and we have OH stretch over here at 3300. There's evidence that all the protein did not get cleaned away, but that's somewhat off topic.
Q So just let's go through and see what their conclusions were, okay?

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A Sure.
Q "From the spectra generated and comparisons to the ATR and FTIR microscope spectra presented earlier, the following conclusions are made: Unstabilized polypropylene is relatively easy to photooxidize; photooxidized polypropylene exhibits a number of species based on IR absorption frequencies," right? We talked about those, some of the carbonyl groups that demonstrate polypropylene degradation due to the oxidative pathway, right?
A Yep, as long as -- as long as you and I understand that they've used the word "polypropylene" in 1 and 2 and not Prolene.
Q Okay. Let's continue to read this, okay? "Formalin solution appears to have little effect on the oxidized polypropylene surface and no effect on the protein removal with soluene," right?
A Yep.
Q So they're saying they're pretty -- that the -- they're easily able to remove protein with the -- with the soluene
A After 10 seconds -- after 10 seconds and 10 minutes of laboratory composure, correct.
Q "No differences were noted between protein

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coated films that were subsequently oxidized and oxidized films that were protein coated, even after soluene treatment," right?
MR. HUTCHINSON: Objection.
Q (By Mr. Thornburgh) That's what it says?
MR. HUTCHINSON: Are you asking what that document says?
Q (By Mr. Thornburgh) That's what it says, correct?
A That's what it states. That's what No. 4 states.
Q And then No. 5, "The soluene treatment not only removes surface protein but also alters the oxidized polypropylene surface. The surface shows mostly anionic or salt (COO) species with some trace amounts of ketone and acid species remaining. Lower molecular weight species of the oxidized polypropylene appear to have been removed with the protein. These observations were noted only on the polypropylene films. Spectra of soluene treated explants generally have been shown to" -- "have shown a retained oxidation band at 1720 yet reduced protein bands." Did I read that correctly?
A You did.

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Q So they're showing that these explanted materials that are treated with formalin and then subsequently cleaned showed oxidative bands of 1720 that were able to be observed and the protein bands were able to be reduced through the soluene treatments, right?
MR. HUTCHINSON: Object to form.
THE WITNESS: The oxidation was induced on the -- on the polypropylene samples.
Q (By Mr. Thornburgh) Yeah, I get that.
A Okay.
Q They're trying to prove a point here.
MR. HUTCHINSON: Dan, stop arguing with the witness. Do you understand me?
Q (By Mr. Thornburgh) They're trying --
MR. HUTCHINSON: Dan, do you understand me?
MR. THORNBURGH: I hear you.
MR. HUTCHINSON: All right, well, good. I want you to understand me. Please do not -- please do not argue with the witness, okay?
MR. THORNBURGH: I'm just -- I'm trying to -- I'm not trying to be -- I'm not trying

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to be a jerk. I'm just trying to have a conversation with you.
MR. HUTCHINSON: I understand that, but your face is all red, your ears are turning red. What I'm asking you to do is not argue with the witness. Do you understand me?
MR. THORNBURGH: I hear you.
MR. HUTCHINSON: Okay.
MR. THORNBURGH: I'm not trying to be disrespectful.
MR. HUTCHINSON: Thank you.
Q (By Mr. Thornburgh) I'm just trying to go over this, what I think is an important study that was done by Ethicon in 1984 which tested your theory and reached a conclusion that contradicts what you're --
A That's patently not true. It is not contradicting anything I've said. At the end of the day, this document is basically just telling me that soluene does not have any effect -- when you clean a fiber or film it with soluene, it doesn't have any negative effect on the actual polypropylene itself. That's all this document ultimately tells me at the end of the day.
And any type of connection you're trying to

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make between tissue existence and tissue removal, it all has to be tempered by the fact that the samples were only dipped inside of these serum proteins for 10 minutes and 10 seconds respectively. So there's just -- there's not a lot here. In other words, you know, I don't know where we're going with this conversation, but it does not dispute the fact that you get a crosslinked polymer long-term in formalin.

Q Which is not on the -- not on the 10 seconds. How long does it take?

A You said --

Q When I asked you before, you said it was immediate.

A You could certainly have had some crosslinking at 10 seconds and 10 minutes, but it wasn't fixed enough to really have much of an effect. And the soluene washing it away rather readily, I think is evidence of that. I just don't -- I don't take a lot of stock in this in terms of it disputing that a known fact, which is a crosslinked polymer, takes place inside a formalin fixed storage.

Q You'd agree with me that the conclusions that they reach are different than those that you --

A No, I would not agree with you. I would not

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agree with you.

Q Okay. Do you disagree -- you disagree with the conclusions that they reached?

A I just stepped you through my interpretation of the conclusions, and I think that they're innocuous and off topic.

Q Do you disagree with the conclusions that they reached?

MR. HUTCHINSON: Objection. Been asked and answered.

THE WITNESS: I just -- same answer.

Q (By Mr. Thornburgh) You didn't answer my question.

A I did. I stepped you through them. I'm telling you that they're innocuous, they're off topic. I don't agree or disagree with them.

Q When formaldehyde or formalin is used and the formaldehyde crosslinking occurs, does that increase or decrease the molecular weight?

A Of what?

Q Of the Prolene explant.

A It does not have any effect on the molecular weight of the Prolene material. The crosslinking that's taking place is proteins and formaldehyde

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monomer that's inside the formalin solution. They chemically react, they crosslink, and they make some -- they make a proteinaceous crosslinked polymer on the outside of the fiber.

Q So no change in the molecular weight?

A Of the Prolene, no. It's separate from that.

Q Okay.

A We're talking about a layer of material that's actually building and developing inside the formalin solution.

MR. HUTCHINSON: Now let's take about a five-minute break.

MR. THORNBURGH: Sure.

MR. HUTCHINSON: Good.

THE VIDEOGRAPHER: We are now going off the video record. The time is currently 3:46 p.m.

(Recess taken.)

THE VIDEOGRAPHER: We are now back on the video record. The time is currently 3:53 p.m.

Q (By Mr. Thornburgh) Doctor, in your expert report, you cite to the dog study and analyze the dog study, right?

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A Correct.

Q So let's talk about the dog study for a little bit, all right?

A Okay.

Q That study was started in 1985; is that correct?

A That is correct.

Q And it lasted for seven years, right?

A It did.

Q It was supposed to be ten years, but it lasted seven, right?

A Correct, it did.

Q And in that study, dogs were implanted in their hearts with different suture materials, right?

A Correct.

Q Prolene was one of those materials that was tested?

A Correct.

Q And PVDF was another one, correct?

A Yes, it was.

MR. HUTCHINSON: Excuse me, he may be trying to find -- are you trying to find the dog study?

THE WITNESS: I'm good.

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MR. THORNBURGH: I've got --
MR. HUTCHINSON: Okay.
MR. THORNBURGH: I've got exhibits here. I can --
THE WITNESS: Yeah, either way, I'm good.
(Discussion off the written record.)
(Exhibit 14 marked for identification.)
Q (By Mr. Thornburgh) So let's look at the -- I have the two-year dog study right now. Let's just look at that and see -- it gives us a little bit of a summary. Marked as Exhibit 14 a two-year dog study, September 20th, 1988.
So in this dog study, am I correct that the test materials were Prolene size 5-0 and PVDF size 5-0 and then Ethicon and Novafil of the same size?
A Correct.
Q And have you reviewed the protocol in this study?
A I have.
Q And it's listed -- if you go to ETH.MESH No. 11336075 of Exhibit 14, part of the protocol says that after the explantation -- after explantation, the explant sample is immediately -- "Immediately after

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explantation, one strand of each sample was randomly selected and without being allowed to dry placed in a capped, properly labeled test tube containing sterile deionized water," right?
A Correct.
Q The labeling -- I'm sorry. The other five strands of each sample would be examined for surface damage as described by Ethicon's finished goods specifications, correct?
A Correct.
Q So in this case, they would take a random sample and they would immediately -- once they explanted it, they would immediately put it in sterile deionized water and take it up for sample testing, right?
A Correct.
Q So it wouldn't -- wasn't put into formaldehyde, right?
A Correct.
Q It wasn't put into formalin; it was just put into deionized water?
A Correct.
Q And this study was going to be -- was looked at at the two-year period, the five-year period, and

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the six-year 10-and-a-half month period, and the seven-year period, right?
A Correct.
Q And different techniques were used to analyze the mesh materials during parts of -- or different -- during different intervals of the 10-year study?
A Correct.
(Exhibit 15 marked for identification.)
Q (By Mr. Thornburgh) Marked as Exhibit No. 15 the five-year report from the 10-year dog study.
Okay. And again, at this interval, the sutures were explanted and analyzed, right?
A Correct.
Q And if you look at page 2 of the report of Exhibit 15, ETH.MESH.11336475, it says "SEM of PDVF Explants," that there were no cracks or abrasions found in any of the explants at five years, right? Am I correct?
A Yeah, I'm just confirming the -- yes, correct.
Q Do you know what -- you know what PVDF is, right?
A I do.
Q Okay. And PVDF is another polymer?

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A Fluorinated polymer, correct.
Q Uh-huh. And Ethicon -- have you looked at studies by Ethicon or internal documents by Ethicon where they were considering replacing Prolene with PVDF?
A I know -- yes, I've seen some memos that talk about the alternative material candidates.
Q And in this dog study, at the five-year mark, the PVDF remained without cracks, but the explanted sutures from the Prolene explants -- sorry, on explants from dogs 212 and 218, a few cracks -- cracked areas were observed. Both of these sutures came out of Site 4, right?
MR. HUTCHINSON: Object to form.
THE WITNESS: Correct.
Q (By Mr. Thornburgh) And so the conclusion that was drawn by Ethicon's scientists was that after five years in vivo, the PVDF 5-0 suture was the only explanted material from five dogs which did not show any surface damage due to degradation. Out of the seven Prolene sutures, two revealed cracking, right?
A That's what it says.
Q And then again on the next page, page 3, it says the Prolene suture intact at two year -- at the

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two-year point showed signs of degradation at five years, and that the only intact surface after five years was the PVDF explants, correct?
A Correct. But they're equating signs of degradation with just visual observations of crack.
Q Well, do you -- do you disagree with that conclusion in 1990 by Ethicon's scientists?
A If you're interpreting the word "degradation" as degrading -- degradation of the polymer, I'm absolutely disagreeing with it.
Q And there are some images of the explanted sutures which show degradation -- which show cracking? I'm sorry.
A They show surface cracking, correct.
Q That's on ETH.MESH.11336483?
A Correct.
Q And you don't believe that's degraded polypropylene -- or degraded Prolene, correct?
A Correct.
Q What is your opinion as to the surface morphology that's being observed on the SEMs?
A I'm not sure I understand your question.
Q Do you have an opinion as to what is the cracked layer that is observed on the SEMs?

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A Yeah, of course I do.
Q What's your opinion?
A Let me tell you what we -- what we know. We know that the cracked layer is not oxidized Prolene. We know the cracked layer is not Prolene. And we know it has a biological component to it.
Q Okay. So the cracked layer is not -- I just want to make sure I understand it -- is not oxidized Prolene, we know that the cracked layer is not Prolene, and we know it has a biological component to it. So what is it?
A I just told you what is it. It's a material with a biological component to it.
Q Similar to the cracks that we observed in the Wood article?
A They're --
MR. HUTCHINSON: Object to form.
THE WITNESS: They're transverse cracks. I don't know if I'd characterize them as similar.
Q (By Mr. Thornburgh) We saw transverse cracks on the Wood article, right?
A Correct, but all -- if you look at the totality of all the micrographs in this matter and all

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the research that's been done, there's variance of this crack pattern, there's variance of degree of cracking, so I would not use that word "similar." They both have circumferential cracks, and I'd leave it at that.
Q And the study went on and at 10 years and -- or six years and 10-and-a-half months, a dog died and they analyzed this dog just prior to the seven-year interim period, right?
A Correct.
(Exhibit 16 marked for identification.)
Q (By Mr. Thornburgh) I'm handing you what's been marked as 16. Let me ask you a question. In your expert report, when you are talking about some of the characteristics of polypropylene, Exhibit 2, page 12, you say that -- you have a "Molecular Weight" section and you say that, "During synthesis, polypropylene monomers are converted into polypropylene macromolecules of differing lengths. The lengths of polymeric chains are defined by the number average (Mn) and weight average (Mw) molecular weights. Typical molecular weight values for commercial polypropylene vary from 222,000 [sic] to 700,000 g" -- what's that, grams per mole --
A Grams per mole, correct.

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Q -- "depending on a number of variables including the specific catalyst used."
What is -- what is the differing values that can influence the variability from material to material?
A Oh, temperature, pressure, reaction time in the vessel, those can all influence molecular weight as they go through the synthesis process.
Q It says that, "There is a degree of randomness associated with the synthesis of most commercial polymers. The total number of monomeric units contained within each polymer chain will vary within a given sample." What does that mean?
A It means that when I polymerize, when I make polymers, I'm going to make polymers which are just long chains of repeat units. Those individual chains at the molecular level all vary in length by a little bit. So I'll have chains that might be -- you know, I'm going to do this arbitrarily on the table. I might have chains that are this long, this long, this long (indicating), and so on, and the molecular weight average is the actual average of those lengths.
Q Okay. So to try to control the variables that happen from -- to try to control the variables in

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a molecular weight test, you'd want to use a control that's as identical to the test material as possible, right?

A Maybe you could rephrase that one.

Q Yeah, I'm just trying to understand. So I'm not a scientist. So if there are variables or variability between one polypropylene to another polypropylene in the molecular weight, to -- if I'm going to do a study, I want to try to compare the same polymer as a control to the test article; is that right?

A If I want to look at -- are you suggesting that you're trying to investigate changes in molecular weight?

Q Yeah.

A And you need a baseline number?

Q Yeah.

A And the baseline would -- you would want the baseline to be representative of the original material; is that what you're suggesting?

Q Right, yeah.

A I'd say in general that makes sense.

Q Okay, because you want to -- you want to -- you want to reduce the variability?

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A Well, you need a reference point.

Q Uh-huh.

A I mean, if you're going to look at a material that's aged under whatever conditions and you want to know if it has degraded and you want to do that by quantifying its molecular weight, you need a reference sample to be able to say yes, it actually did degrade, it actually did shift from some sort of baseline.

Q Okay. So you want to use the same suture, for example?

A You certainly want to use the same material that's seen the same thermal history, processing history.

Q So if I'm -- so, for example, if I'm going to test Prolene mesh 6 mil, I want to use as my control the Prolene mesh 6 mil to reduce the variability as much as possible? To control, right?

MR. HUTCHINSON: Object to form.

THE WITNESS: Ideally, but if you use, say, a 5-0 as a reference versus a 6-0, I mean, the polymerization process that we've talked about happens well before processing, right, so this is -- this is the synthesis of the material. You have raw monomer in a

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pressure vessel with temperature, with time, and I get a reaction to take place because I catalyze it. We talk about that on page 12, okay?

And that building of those chains that we just talked about take place in the reactor, and now I convert that raw material into fiber. So the baseline molecular weight is largely dependent on the synthesis and polymerization process that we just talked about.

Q (By Mr. Thornburgh) Well, one of the things that can influence the polymer is the -- I think you just said it -- the extrusion process --

A Sure.

Q -- right?

A Yeah. And I'm saying there really shouldn't be and wouldn't be a major difference in the extrusion process between 5-0 and 6-0 that would influence the molecular weight.

Q But they -- you say here that -- it says there is a degree of randomness associated with the synthesis of most commercial polymers. The total number of monomeric units contained within each polymer

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chain will vary within even a given sample.

A Yes, and that's why you do a molecular weight analysis. You actually characterize the entire distribution of the chains in your sample, and then I take an average of that number. It's common practice within polymers.

Q And even within a given sample -- or, I'm sorry, the values of commercial polypropylene will vary in terms of molecular weight from 220 to 700 grams per mole, and that's a pretty significant difference from one commercial polypropylene to another?

A Sure, but you have to remember that there are literally thousands of grades of polypropylene out there. Some are designed for melt spinning, some are designed for injection molding, some are designed for thermoforming and extrusion. All of these -- all of these processes require different types and grades of polypropylene to get through those manufacturing processes. This is a viscosity discussion, how viscous the material is in its molten state. So that's why it's not uncommon to have this large spread across the thousands of grades that are out there. We're talking about a very specific grade Prolene with a very controlled resin supply chain.

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Q So -- but as a scientist, you want to control as best -- as well as you can the degree of variability, right?
A In a manufacturing process, I would say that that's a general goal, is to minimize variability.
Q Not just as a manufacturing -- manufacturer, but as a scientist, you want to -- you know, you want to use your -- a control that is the same as the test article?
A I don't want to get off --
Q It seems like --
A -- I don't want to get off on a tangent, but in my scientific study, if I'm looking at -- trying to explore a hypothesis, then I am going to vary certain variables to get a response. So I think just saying blanketly that I want to minimize variation in all of my scientific studies, if I did that, I wouldn't have a scientific study. I have to vary something to get a natural response in my scientific experiment.
Q But if you're not trying to explore a hypothesis, but you're trying to confirm, for example, the molecular weight of a given -- of an explanted suture, for example, you want to compare a 5-0 suture to a 5-0 control?

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MR. HUTCHINSON: Object to form.
THE WITNESS: Ideally, but it doesn't undermine any of the data that we've seen.
Q (By Mr. Thornburgh) It makes the data less reliable?
MR. HUTCHINSON: Object to form.
THE WITNESS: I disagree.
Q (By Mr. Thornburgh) It increases the variability?
A I disagree.
Q Have you looked -- have you looked at the molecular weight of a 5-0 Prolene suture and compared it to the molecular weight of a 4-0 Prolene suture?
A I don't recall.
Q Have you asked for data from Ethicon to show you what the molecular weight is in a 5-0 compared to a 4-0?
A No, I haven't asked for that.
Q You'd want to look at that, right, to determine whether or not there is too much variability?
MR. HUTCHINSON: Same objection.
THE WITNESS: Knowing what I know about this resin, how it's been used, I haven't seen any data that would suggest going from

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one filament size to the next is going to shift my molecular weight statistically.
Q (By Mr. Thornburgh) Well, the filament size -- you just indicated that there could be a number of different things that could affect the randomness even within a given sample?
A During synthesis, synthesis.
Q Hold on a second, all right. On page 12, you say, "Since there is a degree of randomness associated with the synthesis of most commercial polymers, the total number of monomeric units contained within each polymer chain will vary from a given" -- "within even a given sample."
A Yes. You never get monodispersed polymer in a synthesis -- in a -- in a large-scale manufacturing environment that synthesizes commercial grades of polymer.
Q You also want to use -- well, do you know what changes occurred in the manufacturing process from 1985 until the seven-year study was done in 1992?
A You'd have to refresh my memory of the document.
Q Well, we know one of the things that changed was they reduced the level of the Santanox, right?

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A Correct. You asked me about the manufacturing process.
Q But one of the things that they did is they reduced the level that they put into the Prolene resin of Santanox, right?
A Correct.
Q That's part of the manufacturing process, right?
A I would have characterized that as a change in the formulation, but --
Q Uh-huh.
A -- regardless, yes.
Q Uh-huh. And do you know what other changes occurred at Ethicon concerning the Prolene sutures?
A You'd have to show me a document.
Q Different extrusion machines, so if you go from one extrusion -- or let's say a blender, you go from one blender to another -- you change from a blender to a different blender, that could impact the -- or -- impact the variability of the molecular weight, right?
MR. HUTCHINSON: Object to form.
THE WITNESS: No. No, because blending is just going to blend the polymerized

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polymer and the additives that you're putting into it into the final resin, so --
MR. THORNBURGH: Well, so what other --
THE WITNESS: -- I don't agree with that.
MR. THORNBURGH: Sorry.
Q (By Mr. Thornburgh) What other changes could impact the variability of the molecular weight from within one sample? You say here the synthesis. What's "synthesis" mean?
A Synthesis is what I talked about a few minutes ago. That's the conversion of small molecules into one large polymer, one large molecule. That's what synthesis is.
Q So how do you convert it from one molecule to a larger molecule?
A Just like we describe in the report, you initiate it with a catalyst, so you start a chemical reaction, and each small molecule then reacts with its neighbor until you have a large macromolecule. And that's what the polypropylene is, is a large macromolecule with repeat units along its structure.
Q And what is the catalyst?
A There's all sorts of catalysts. I think we

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mentioned a few in the report. A Ziegler or Natta catalyst can be one or two of them. I'm not specifically sure.
Q A what or a what?
A Ziegler or Natta catalyst is often used with polyolefins.
Q Do you know if Ethicon changed its catalysts from 1985 until --
A No, but all the molecular weight data tells us that everything is A-okay, we're getting consistent molecular weight data across the board, so nothing appears to be changing.
Q Well, did you -- did you -- have you -- well, let me ask you this question: What is the molecular weight of the control 5-0 that was ran in 1985?
A I don't know if I've seen a document that says what the control of the 1985 5-0 is.
Q Doesn't it seem reasonable, as a scientist, that if you're going to do a study that looks at molecular weight and you start that study in 1985 with the intention of doing molecular weight studies on 5-0, that you run a control GPC of the Prolene 5-0 to see what the molecular weight is in 1985?
A There is not a significant enough difference

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between the fiber diameter of a Prolene 4-0, 5-0, 6-0 that's going to translate into any statistical difference in the molecular weight.
Q Tell me what the control run of the 5-0 was -- well, tell me what the molecular weight control run of a Prolene 5-0.
A It's the same answer. I don't -- I can't find one. If you have one, I'd be happy to look at it. What I've seen in some of the molecular weight data from the dog study, it was a 4-0 baseline material that's used.
Q Oh, the dog study was a 4-0 baseline?
A That's what I have for data in front of me.
Q And the study was -- the implanted Prolene sutures were 5-0, right?
A Correct.
Q And you don't know what the molecular weight is of the Prolene suture 5-0 in 1985?
MR. HUTCHINSON: Same -- object to form.
Q (By Mr. Thornburgh) I mean, if you're going to do a prospective study --
MR. HUTCHINSON: Dan, is that question withdrawn?

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MR. THORNBURGH: Withdrawn.
MR. HUTCHINSON: Okay.
Q (By Mr. Thornburgh) If you're doing to a prospective study --
A Uh-huh.
Q -- right, of these dogs and the end result seven years later is to look at the molecular weight, in 1985, you want to run a control of the 5-0 Prolene, that's the way good science is done?
A Ideally, but there's nothing wrong with using a Prolene 4-0 suture here. There's nothing that tells us that the molecular weight number and data we get is not consistent with 5-0.
Q But you don't know what the 1985 5-0 molecular --
A It's the --
MR. HUTCHINSON: Guys, I'm sorry, one at a time. Dr. MacLean, you can finish your answer. Mr. Thornburgh will gladly allow you to do that.
THE WITNESS: It's the same resin formulation, it's the same base polymer, it has the same molecular weight coming out of the synthesis process that we've talked

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about. The differences, if any, between spinning a 5-0 and 4-0 fiber are not going to have a statistical influence on the molecular weight. That's my opinion.

Q (By Mr. Thornburgh) And you're reaching that opinion without looking at the data of a 1985 control 5-0 Prolene, correct?

A I'm reaching that opinion on being in the plastics and polymer industry for 20 years, being around polymers that have been synthesized, that have been compounded, that have been extruded, that have been manufactured. And I'm telling you, based on my experience, I would not expect a difference in molecular weight between a 4-0 and a 5-0 specimen.

Q The better scientific thing to have done -- let's just throw it on the table. The better and the best scientific -- the good manufacturing practice -- the good laboratory practice, right -- I've seen -- I've seen -- you've talked about good manufacturing practices, you -- I think you've maybe lectured about it at maybe school or somewhere, I forget, but I've seen you talk about it somewhere. You're familiar with good manufacturing -- or good laboratory practices, GLP, right?

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MR. HUTCHINSON: I'm sorry. Dan, what --

MR. THORNBURGH: Let me withdraw the question.

MR. HUTCHINSON: Thank you.

MR. THORNBURGH: Withdraw the question.

MR. HUTCHINSON: You were talking about throwing something on the table, and you lost me after that.

MR. THORNBURGH: Let me withdraw the question.

THE WITNESS: Okay.

Q (By Mr. Thornburgh) You understand what good laboratory practices require, right?

A I understand what good science requires. I understand in some cases you don't have a perfect, an ideal set of conditions to work with. And there is nothing wrong with using a 4-0 suture as a baseline here with the same exact resin formulation, same manufacturing process, to establish a baseline in the absence of a 5-0.

Q And --

A There's nothing wrong with that.

Q And a change in the additives, including an

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antioxidant?

A We don't know that. You're going to cite the document, I know you are, but we don't -- I don't think we know, unless you can point me to a document, when these reference samples were manufactured.

Q Would that be important?

A Not really, because the only one change that we've talked about is this -- I would argue negligible or slight change to the one antioxidant. That is not having any bearing on the molecular weight synthesis process that I've outlined for you. Those are mutually exclusive. There's no interaction between those two things.

Q Would it change your opinion if the standard -- or the average molecular weight of 1985 Prolene 5-0 was statistically different than the molecular weight of a pristine Prolene 4-0 in 1992?

A I'd need to see the data.

Q Would it -- would that be important to you, if there's a statistical difference?

A It may, it may, but I'd need to see the data.

Q Did you notice that before today?

A Notice what?

Q That the test suture was Prolene 5-0, but the

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control in 1992 was Prolene 4-0.

A Oh, sure, yes.

Q Did you ask Ethicon's attorneys if they had any data on the molecular weight of a 1985 Prolene 5?

A No, because if you look at the data --

MR. HUTCHINSON: Objection.

THE WITNESS: Sorry, Chad.

MR. HUTCHINSON: That's all right. I'd just object to form. Counsel, I think you meant 4-0, but that's fine.

Q (By Mr. Thornburgh) Did you ask Ethicon's attorney if they had --

MR. HUTCHINSON: You can answer the question.

MR. THORNBURGH: Let me make sure I have it right.

Q (By Mr. Thornburgh) Did you ask Ethicon's attorneys if they had any data on the molecular weight of a 1985 Prolene 5, which was the test article, so you want to look at the 1985 5-0 as the control, that would be the ideal thing to do?

A It would be the ideal thing to do, but when I look at the data that's been compiled, it is clearly obvious to me that the molecular weight is right in

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line with all the other samples and there's no shifting -- there's no statistical shifting taking place.
Q In the 6-year-10-and-a-half month report, the conclusions that were reached was that approximately 50 percent of the Prolene suture surface was cracked due to degradation. Do you disagree with that?
A Can you -- I just want to -- can you read that to me one more time?
Q Yeah. Conclusions on ETH.MESH.09888100.
A I'm sorry --
Q Exhibit --
A -- I might be in the wrong exhibit.
Q I'm sorry. Exhibit --
A Sixteen?
Q -- 16.
A Okay. And the Bates number one more time.
MR. HUTCHINSON: One hundred.
THE WITNESS: One hundred?
MR. THORNBURGH: Yep.
THE WITNESS: Got it. Okay.
Q (By Mr. Thornburgh) You see the conclusions there?
A I do.

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Q The only explanted suture still undamaged after 6 years and 10-and-a-half months in vivo is the 5-0 PVDF suture, right?
A That's what it says.
Q Approximately 50 percent of the Prolene surface was cracked due to degradation; do you disagree with that?
A If you interpret Prolene suture surface as being the actual Prolene material, I absolutely disagree with that. I don't -- I don't -- I don't disagree that there was probably a 50 percent calculation or estimation made, but I disagree that the cracking was taking place in the Prolene.
Q You disagree that it was degraded, right?
A Oh, without a doubt. The data tells us that.
Q Okay. So this is another scientist, Dr. Lindemann, that you disagree with --
A What page you are you on?
Q -- who -- 102, is the person who signed the report.
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) You disagree with Ethicon's internal scientist, Dr. Lindemann?
A Correct. He's made the same mistake that

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almost all the other researchers have made. They have equated the appearance of cracking to degradation. And it's fundamentally flawed.
MR. THORNBURGH: Change the tape.
THE VIDEOGRAPHER: We are now going off the video record. The time is currently 4:26 p.m. This is the end of Tape No. 4.
(Recess taken.)
THE VIDEOGRAPHER: We are now back on the video record with Tape No. 5. The time is currently 4:42 p.m.
Q (By Mr. Thornburgh) Doctor, before we went off the record, we were talking about the 6-year-10-month -- 10.5 month study, and we were then going to talk about the seven-year data on the Prolene study.
MR. THORNBURGH: Go ahead and mark this Exhibit No. 17.
(Exhibit 17 marked for identification.)
Q (By Mr. Thornburgh) This is the October 15th -- it's the October 15th, 1992 seven-year data for the 10-year dog study. See the "IR and IR Microscopy" section?
A I do.

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Q So they performed some chemical analysis, right?
A They did.
Q Using infrared?
A They do.
Q And they did -- they analyzed the Prolene sutures that were explanted, correct?
A Correct.
Q This is the first time they actually did the IR analysis, right?
A Correct. I believe you're correct.
Q And on October 15th, 1992, in this report the authors conclude that, "The IR microspectroscopy was used to examine cracked areas of Ethilon, Novafil, and Prolene explants. IR spectra obtained for cracked Prolene specimen (Figure A) showed possible evidence of slight oxidation." Did I read that accurately?
A Yes. "Possible evidence of slight oxidation," that's what it says.
Q Do you disagree that they found possible evidence of slight oxidation?
A I do.
Q Okay. And I assume that you believe that they were seeing protein?

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A Correct. Well, it's either protein and/or those aliphatic ester compounds that we talked about earlier.
Q The ester compounds?
A Correct.
Q And is that what -- is that what you're opining is the -- what causes plasticization?
A Correct.
Q And why is that your opinion?
A Well, because you have to look at the totality of the data. So let's look at a couple of things to kind of show that. This is what --
Q So for the record, you're referencing Exhibit 2 of your expert report -- or, no, you have attachments to your expert report, which include some dog photos, right?
A Correct.
Q Those aren't actually in your report that you submitted?
A Correct. These are just additional documents. This one ends in 0674, depo -- it's ETHICON.MESH.0006474.
Q Okay. And that's dog -- that's seven-year dog explant from what dog?

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A This is from Dog 2008. This is Site 2.
Q Okay. And why is it your opinion that -- what's your opinion? What are you trying to show us?
A Okay. So in this -- in this micrograph, I'm actually showing you a stretch of a fiber from Site No. 2, and it has this -- what people have coined or termed "severe degradation." You've got a number of different concentric transverse cracks that are happening in parallel along the length of the suture, and everyone looks at this specimen, finds the carbonyl functionality, and says it's oxidized.
And then not only do they say it's oxidized, they say this is signs of embrittlement. So -- but when you look at the actual data, and we actually have tensile data for Dog 2008, Site 2, if you look at the tensile properties, there is no embrittlement taking place. As a matter of fact, you see an increase of roughly a hundred percent increase in ductility.
Q Tell us where the tensile data is that you're referencing.
A Sure. I'm on ETHICON.MESH.11336182.
Q Okay. And this is tensile testing that was done at seven years?
A That's correct.

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Q And this is in Exhibit 2, right?
A It is in Exhibit 2, correct.
Q Okay. And the Prolene control is what?
A It's -- you'd have to look at the data on a separate page. Let's just stick with me for one second. So about two-thirds of the way down on the table that's on the ETHICON.MESH document that I just read, you'll actually see a series of data points for Prolene.
And there's one particular line, "Prolene, Dog 2008, Site 2," so that is the exact dog and site location that's represented by the image that we just spoke about on Ethicon document ending in 6474. And if you look at the tensile elongation data with that particular type of fiber, I have achieved 70.76 percent elongation at break.
Q Okay. And they're comparing -- to get the elongation changes, they compared the Prolene --
A Well, this is not a -- let's be careful. This is not a change. This is the actual number, the amount the material stretched before it actually broke in the tensile test.
Q Okay, but you have to compare that to a control, right?

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A We do, and we do that.
Q What's the control?
A The control data, off the top of my head, is approximately 37 percent. I'll get you the exact number. So reading off of my chart in my larger expert report, on page 45, I'm in Figure 8, top right-hand corner. Elongation at break for Prolene at times zero, the control, is approximately 37 percent off of the graph.
So as we have survived seven years in vivo, we have actually doubled the amount of ductility and the amount the material can stretch despite the fact that we see a carbonyl peak and despite the fact that we see what some people say a large amount of cracking is on the surface of the fiber.
In addition to that, if you want to talk about true degradation, you look at the molecular weight data for seven years, and we see no change. There is no difference, no statistical difference in the molecular weight values for a seven-year dog study compared to what the times zero molecular weight was.
So between no molecular weight, the doubling of elongation, and despite the fact that we see cracking in the carbonyl peak, it's clear that the

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material is not degrading. Your experts are claiming that if I've got degradation, I must have embrittlement, and we are seeing the exact opposite. We do not see embrittlement. We see a shift in the exact opposite direction. You can't have that both ways.

Q So you would see a reduction in the tensile strength, right?

A In the elongation. Plasticization in polymers, you're going to have two things that are definitely going to happen. You're going to have an increase in ductility, which we just stepped through. We're going to have a slight reduction in modulus because you're getting more flexible, the material is actually becoming more compliant. And the seven-year dog study tells us that the -- you know, the average breaking strength is really unaffected over the seven-year period.

So -- and if you look at the bulk physical properties that are important to this mesh in terms of being pliable, ductile, and maintaining its strength, they're all there. And at the end of the day, this coating material, in terms of truly identifying what it is, is an academic exercise. It's an academic exercise

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because it does not matter. Whatever it is, even though it has a carbonyl functional group perhaps associated with it, it does not matter.

Q Okay. Let me -- let's go back and talk about all those issues.

A Sure.

Q Okay?

A Sure.

Q Number one, where's your data? What data are you relying on for your chart concerning the control tensile strength for Prolene 5-0? Where is that data at?

A It's the same discussion we had. So the data has been -- the data has been either normalized or the 4-0 tensile strength has been used.

Q So they used -- so, again, the test model or the test -- they tested in this dog study a 5-0 suture in 1985 and they compared the tensile strength in 1992 to a 4-0 suture, correct?

A They certainly did that in the molecular weight. I just don't recall off the top of my head if they did that for the tensile strength.

Q Well, let's look real quick.

A Sure.

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MR. THORNBURGH: Let's go off the record for a minute.

THE VIDEOGRAPHER: We are now going off the video record. The time is currently 4:51 p.m.

(Off the record.)

THE VIDEOGRAPHER: We are now back on the video record. The time is currently 4:56 p.m.

Q (By Mr. Thornburgh) Okay, before we went off the record, you were -- you had said that one of the reasons why you believe that the Prolene did not degrade as a result of oxidation was because there was 10-year data collected at the seven-year period of both tensile strength and molecular weight.

A And elongation and modulus, correct.

Q Okay. And you had -- and what page are you looking at?

A I'm looking at the -- I'll call it the raw data from the 10-year dog study. It ends with ETHICON.MESH.11336084.

Q Okay. And so the date of the memo is August 18th, 1988, right?

A It is.

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Q And the title of this document is "Ten-Year Prolene BSR Study," right?

A Correct.

Q And what we know about the tensile strength here is that they only looked at Year 1 and 2?

A In this data set, correct.

Q Okay. And in Year 1 and 2, we know from looking at the two-year dog study there wasn't any evidence at the two-year interval of degradation even in the Prolene suture, correct?

A Rephrase that question.

Q We know from looking at the studies that there was no evidence of degradation in the two-year period of the 10-year dog study, correct?

A Based on what? How do we know that?

Q We looked at the dog study and we looked at the five-year dog study that said Prolene is now degraded compared to the two-year mark when there was no degradation.

A Oh, you're referencing that text.

Q Yes. Do you remember that?

A I do, sure.

Q Okay. So there was no evidence of surface cracking on the sutures at two years, right?

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A Correct.
Q And there was no conclusion that those -- at the two-year period that there was any degradation, right?
A Correct.
Q So then they issued a 10-year Prolene BSR study in 1988 showing only data up to two years, correct?
A In that memo, correct.
Q Okay. So where's the other memo that you're referencing?
A It's on ETH.MESH.11336182.
Q Okay. And this is dated October 19th, 1992?
A Correct.
Q And it says, "Attached table shows the physical properties of explanted and baseline samples of size 5-0 Ethilon, Novafil, Prolene, and PVDF sutures at the seven-year mark of the 10-year BSR study," right?
A Correct.
Q It says the tensile -- if you could look down at the bottom paragraph, "Seven-year testing conditions were based on the one-year and two-year data to keep them consistent throughout the study. Tensile testing

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conditions were 1 in." -- what's that, inch per minute --
A Inch per minute, correct.
Q -- "crosshead speed for the Prolene samples, and 5 inch per minute for all other samples with gauge strength (GL) of 1 inch," right?
A Correct.
Q So they used the data from the one- and two-year data to keep it consistent throughout the study. Did you understand what that means?
A I do. They just -- they made some consistency on the test parameters in terms of the rate at which you pull the fiber in tension between one, two, and seven years, and that's what I would expect them to do.
Q So the seven-year testing conditions were based on the one- and two-year data to keep them consistent throughout the study. I don't understand what that means. So if you can try to --
A Sure.
Q -- explain it to me again.
A Yeah. So what they mean, the testing conditions are essentially the rate at which I pull the fiber to get my tensile properties. This is nothing

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more than taking the suture, placing it in an instrument that allows me to pull it in tension, and I measure how stiff that fiber is, how much stretching it undergoes before it fractures and breaks, and what the ultimate strength of that fiber is as it breaks. And all they're saying is that for consistency purposes, they kept the one-, the two-, and the seven-year conditions the same, which is what I would expect them to do.
Q If you turn the page -- so let me ask you this: At the seven-year mark, did they use the 5-0 Prolene suture as their control?
A It's whatever the control is in the previous Ethicon document that we talked about a few minutes ago. It's the -- there are data points that say unimplanted fibers for each material type, and that's the control.
Q And so they did that for the tensile testing, but not for the GPC?
A It appears so. It appears so.
Q If you turn to ETH.MESH.11336182, which was the back side of the 10-year Prolene BSR study --
A Give me the last three again.
Q Yeah, it's -- well, on mine, it's 182.

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A One eight two.
MR. HUTCHINSON: Of which exhibit?
MR. THORNBURGH: In his -- in his Exhibit No. 4 [sic]. Sorry.
THE WITNESS: I'm on 182.
Q (By Mr. Thornburgh) Okay. So it's where you just were on the 10-year Prolene BSR study. You were just there a moment ago.
A Okay.
Q So go back to where you were when we were looking at the --
A The raw data?
Q Yep.
A Memo, August 18th, 1988?
Q Yeah.
A Dr. Moy?
Q Yep.
A Okay.
Q All right. Turn the page to the second page of the memo with the raw data.
A Now -- hold on a second. Now you're on the seven-year data. Is that what that says?
Q Yes, it's the seven -- because the 10-year data doesn't exist.

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A No, no, that's not what I'm asking. When I turn the page that we were just on, I get a different document, so I'm trying to make sure we're working from the same document. That's all.
Q This is from Mark Cofone dated October 19th, 1992.
A I thought we were just on the August 18th, 1988 document.
Q No. That was -- that was -- previously we were.
A Okay.
Q So let me --
MR. HUTCHINSON: Dan, if you have a copy of the document to give him, I think that would help us --
MR. THORNBURGH: Here we go.
MR. HUTCHINSON: -- so we're all on the same page.
MR. THORNBURGH: Just mark this as Exhibit No. 18.
(Exhibit 18 marked for identification.)
(Discussion off the written record.)
Q (By Mr. Thornburgh) Here you go. Exhibit No. 18 is in front of you. We're looking at the data

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from the seven-year BSR analysis, right?
A Yes, correct.
Q And so if you look at -- if you look right here, for all of the other sutures, the tensile testing conditions were 1 inch per minute crosshead speed, but for Prolene it was switched to -- the Prolene samples, it was changed to 5 inches per minute for all -- sorry, hold on a second. So for Prolene, the testing conditions were 1 inch per minute crosshead speed for Prolene.
A Correct.
Q For all other samples, it was 5 inches per minute for all -- for the rest of the samples. Why is that? Why would they change the protocol for Prolene compared to the other sutures that were tested?
A I don't know why that choice was made. When I read this paragraph, it tells me that the original -- what I'll call time zero or control or unimplanted specimens, when they were tensile tested, the Prolene was tested at 1 inch per minute and the other samples were tested at the 5-inch-per-minute rate. I think they recognized that difference, and just to be consistent throughout the entire study, they stuck with those differences.

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That difference is not -- that difference, even though there is one between the two rates, within the Prolene itself, they maintain the same rate. So we aren't getting a different response from the Prolene because we've -- we haven't changed its test conditions.
Q Well, we have changed the test conditions because we're comparing it to the one- and two-year data, right?
A Yeah, but if you look at the one and two -- I think we just read that they've kept that applied crosshead speed the same based on the type of fiber material that they've used. So Prolene, they maintain the 1-inch-per-minute testing conditions, tensile-testing conditions were 1 inch per minute crosshead speed for the Prolene samples. We just read that same type of text as a footnote on the one- and two-year data. So they're just trying to be consistent amongst the materials that they've -- that they've tested.
Q So they do 1-inch-per-minute crosshead speed. What's the difference between crosshead speed and chart speed?
A Chart speed is actually -- these are old

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instruments. Chart speed is actually you're plotting with an ink charter the data points you're collecting from the mechanical test. So every -- whatever that rate is is how often you're actually putting a dot or a piece of -- a drop of ink on your chart that actually charts this data. So it's just -- it's a very old piece of equipment. They don't use those charts these days. But they're unrelated, and chart speed has no bearing whatsoever on the material properties.
Q All right. But if you look at the August 18th, 1988 BSR study --
A Uh-huh.
Q -- okay -- are you looking at it?
A I am.
Q Okay. It says the conditions used for data analysis were 1 inch per minute crosshead speed (XH) and 10 inches per minute chart speed for the one-year Prolene controls and explants, 1 inch per minute XH and 5 minute [sic] per minute CS for the two-year Prolene samples, and 5 inches per minute and 20 inches per minute for all other samples.
A Correct. So let's break that down.
Q Why are they changing it -- why are they doing it two different -- I'm trying to understand why

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they're doing one-year different than the two-year and the two-year --
A They're not. If you really parse these paragraphs out, the one consistent factor that's talked about here is the rate that's being applied for Prolene. It's 1 inch per minute crosshead speed at one year, it's 1 inch per minute crosshead speed at two years for Prolene, and it's 1 inch per minute crosshead speed at seven years for Prolene. So they have maintained consistency in the rate at which they pull that specimen for all the Prolene samples.
Q Did they report the chart speed at the seven-year period?
A They didn't, but I just told you that the chart speed is irrelevant. It has nothing to do with the mechanical properties. It's just a matter of the chart that gets produced from the data.
Q Okay. And GPC --
A Okay.
Q -- again, for GPC, which was a -- is a bulk analysis to analyze the molecular weight, right?
A Correct.
Q And if we're looking at the same exhibit, 18, on page ending in 218 -- are you there?

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A Two one eight. Am I supposed to be in Exhibit 18 or am I on --
Q Yeah, 18 --
A Okay.
Q -- since we're using it.
A Okay. Okay.
Q Okay. Again, so the -- obviously the control is different than the test article, right?
A It's a different size suture, same material.
Q And if you look at the conclusions and comments, "Comparison of seven-year explants to current 4-0 Prolene sutures indicates no significant degradation," right, that's the conclusion?
A That's correct.
Q Not saying there isn't degradation, they're saying there isn't significant degradation?
A They've used the word "significant degradation" because they're trying to be very scientifically astute here. These molecular weight numbers have -- we've talked about these -- they have ranges to them, and they're just saying that within statistical -- within statistical bounds of the data, that they're all about the same.
As a matter of fact, I mean, if you really

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parse the data, the control molecular weight is -- let's look at weight average for a second. It's 324,000 units. And the two Prolenes from Site 1 and Site 6 are 322 and 323. So there's no meaningful difference between those numbers. You're talking hundreds of thousands of molecular weight units and you're talking in the -- on the order of 1 percent of that is changing between those numbers. There's just no statistical difference between those data. The fact that it goes from 324 to 323 to 322 is probably why she tried -- he or she tried to be safe with this explanation and say "significant," but there's no difference in that data.
Q It's a -- it's a bulk analysis, though, right?
A It is a -- it is a bulk analysis.
Q And a bulk analysis looks at the entire -- the bulk of the entire sample when it does -- when it analyzes the molecular weight?
MR. HUTCHINSON: Object to form.
THE WITNESS: It analyzes the bulk of the material, correct.
Q (By Mr. Thornburgh) Okay. And so if Dr. Barbolt is correct that the Prolene only undergoes

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surface degradation on the outer core or the outer skin, the bulk analysis would not be able to identify a change in molecular weight --
A No.
Q -- a significant change in molecular weight?
A That's incorrect. We've done that analysis. That's in my report. We've used a rule of mixtures. We've used Jordi's data to characterize the degraded -- the alleged degraded molecular weight. And based on our work, based on our analysis, the bulk material analysis would actually catch any shifts that are happening out in the fiber.
Q You assume that the --
MR. HUTCHINSON: I'm sorry.
MR. THORNBURGH: I'm sorry.
MR. HUTCHINSON: No, I'm sorry.
Dr. MacLean, were you finished?
THE WITNESS: I'm finished.
Q (By Mr. Thornburgh) The assumption that you made to reach that conclusion was a molecular -- a depth of 4 microns in the degraded surface, right?
A Correct.
Q Why did you make that assumption?
A Because it's kind of the running number that

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your experts keep using, including Dr. Iakovlev.
Q What page of your report are you looking at?
A Fifty-five.
Q Did you go -- did you measure any cracked depths in any of the analysis done by Dr. Jordi?
A I don't recall whose measurements I've looked at. I know I've seen plenty of micrographs with scales on them that you can take either a direct measurement yourself or do a rough estimation based on the scale bar.
Q So you took the molecular weight data from Dr. Jordi --
A Correct.
Q -- and assumed a surface degradation that is as -- that goes as deep as 4 microns?
A Correct. That's what this analysis is.
Q If the micron -- if the average micron depth was 2 microns, how would that change your analysis?
A You'd have to rerun the calculation. You're going to get probably closer to the bulk number than you are with the 51,000 number that we have at 4 microns.
Q So if you assume 4 microns, it gets you outside of the standard deviation for the molecular

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weight?
A At 4 microns, it does, correct.
Q At 2 microns, it gets you closer to the bulk analysis, which would wash out the molecular weight changes on the surface, they'd be masked by the bulk?
A It could. Yeah, at some smaller crust thickness, you would be within the statistical confines of the original data.
Q And you took no measurements of Dr. Jordi's micron crack depth -- his crack depth -- strike that.
You took no measurements of Dr. Jordi's samples to determine the crack depths of the explants that were actually included in the GPC analysis?
MR. HUTCHINSON: Object to form. Counsel, are you asking if he looked at Dr. Jordi's samples?
Q (By Mr. Thornburgh) Did you -- you didn't go back and -- you didn't look -- did you look at Dr. Jordi's deposition and see what --
A I looked at his Bellew report. He had scores of micrographs of cracked -- surface cracked fibers.
Q Well, the GPC data came from the Lewis report.
MR. HUTCHINSON: Is that a question,

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Counsel?
Q (By Mr. Thornburgh) Do you understand that?
A If you look at what we did, he talks about a specific melt temperature associated with the fiber. And then if you go to the literature and you assume degradation, the corresponding molecular weight assumed with his -- sorry, associated with his suppressed melt temperature is the number that we used. So we used his information from Bellew to get at the molecular weight of what a degraded crust would be, and we coupled that with, I would say, nominal crust thicknesses that we've seen in the micrographs.
Q You're going to have to walk me through that because --
A Okay.
Q -- that was one -- that was one sample in the Bellew case, right?
A It was one sample, but he put it in his report.
Q But it's one -- so you looked at one sample, you assumed that it was a 4 --
A I didn't look at one --
MR. HUTCHINSON: Hey, guys.
MR. THORNBURGH: Let me just finish the

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question.
THE WITNESS: Sure.
Q (By Mr. Thornburgh) You looked at -- you looked at a sample, the Bellew sample, and assumed that it had a crack depth of 4 microns, right?
A Correct.
Q One sample based on -- based on your analysis of the SEM images or what?
A You're mischaracterizing what Dr. Jordi did. If you read what I wrote in my report, it says the conclusion drawn from this is incorrect. Dr. Jordi reported an average melting temperature of the Bellew explanted samples, plural, of 124 degrees C compared to 126 degrees C.
Q You're reading on page 54, right?
A Correct.
Q And so you say, "According to Dr. Jordi, the over 50 degree Celsius decrease in observed melting temperature can be considered proof of sample oxidation."
Okay, so how do you go from 50 degrees Celsius decrease in observed melting temperature to assuming or making an assumption that the crack depth is 4 microns? Is that --

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A I don't. I don't. They're mutually exclusive. So I take his suppressed melt temperature from multiple measurements, not one, and that's 124 degrees centigrade. Then you go out to the literature and you find a relationship, a meaningful relationship between melt temperature and molecular weight. And the molecular weight that would correspond to 124 degrees melt temperature is 4500 units, molecular weight units. So that's done separate. We have now quantified this hypothetical degraded crust molecular weight.

The second part of that analysis is now to do the calculation, to do the rule of mixtures on page 55. You need to -- you need to choose a crust thickness to do the calculation, and we chose the crust thickness based on the thicknesses that were either observed in the micrographs or taken from some of the experts, you know, Dr. Iakovlev's report, things like that.

Q The 124-degree change that you're referring to in Bellew, are you talking about the thermo -- the thermal analysis that he did on the Bellew explant?

A I am.

Q Okay. So he took one measurement of one explant that was treated in sodium hypochlorite, had a -- what showed a decrease in its melt point at 124,

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and then so you used that one data point --

A It's not one data point.

Q Do you have -- do you have Dr. Jordi's expert report with you?

A I don't think I do.

Q Do you have it in this -- right here (indicating)?

A No, I don't.

Q I think I have it. Hold on one second.

MR. THORNBURGH: Let's go off the record. I just want to understand your opinion.

THE VIDEOGRAPHER: We're now going off the video record. The time is currently 5:22 p.m.

(Off the record.)

THE VIDEOGRAPHER: We are now back on the video record. The time is currently 5:29 p.m.

Q (By Mr. Thornburgh) Okay. So in your report, you state that the -- you assume that the crack depth is 4 microns, and you testified that that assumption was based on your review of the Bellew nano thermal analysis; is that correct?

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A Correct. And I was mistaken. I should have looked at my footnotes. That estimation -- I wouldn't call it an assumption -- comes from Dr. Iakovlev's report in the consolidated case, as well as an Ethicon document, ETH.MESH.12831405 and 1406.

Q Okay. So it came from Dr. Iakovlev's report of several different TVT explants?

A Correct. We took an average.

Q Okay. You took an average of how many?

A Well, whatever his data was. I think he shows data from anywhere from less than a micron or about a micron all the way up to 7 plus microns, and we chose 4 as a nominal average.

Q How many years of implantation?

A You'd have to defer to his data. I think it was several years. Seven years, maybe, whatever his data is. We can pull it up.

Q So you don't have -- you don't have the data in here to tell me how many explants were analyzed to reach an assumption that the surface degradation depth would be 4 microns?

A It's --

MR. HUTCHINSON: Object to form.

MR. THORNBURGH: Go ahead.

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THE WITNESS: It's not an assumption. It's based on your expert's data. It's a nominal average of your expert's data.

Q (By Mr. Thornburgh) Hold on a second. Let me ask a couple questions --

A Okay.

Q -- because you understand that Dr. Iakovlev opines that the longer the mesh is implanted in the body, the greater the depth of the bark or the degraded core, right?

A Correct.

Q Okay. So you then used Iakovlev's -- Dr. Iakovlev's data and also looked at Dr. Jordi's thermal analysis, or how did you --

A It was nano thermal analysis data.

Q And then based on both the cracked depths of Dr. Iakovlev's report --

A And Ethicon's, correct.

Q -- and Ethicon's report and Dr. Jordi's nano thermal analysis, you somehow reach a conclusion that the crack depth would be 4 microns, which would -- which would mean that a GPC study would not hide the degradation and molecular weight loss on the -- on the surface area. Is that --

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MR. HUTCHINSON: Object --
Q -- am I understanding it correctly?
MR. HUTCHINSON: Object to form.
THE WITNESS: I'm just going to -- I'm just going to try to explain what I did one more time, and then maybe you can ask me a follow-up question.
We used Dr. Jordi's thermal analysis data to convert to an alleged degraded -- or a hypothetical degraded polypropylene of 4500 atomic units. We took nominal crust thicknesses from your expert's report and some Ethicon documents that are footnoted on page 55, and we ran the calculation. And when you use those data points, you get a statistically different molecular weight. You don't get something that would be so-called washed out.
Q (By Mr. Thornburgh) But is that analysis using the calculation that you would get from GPC?
A It's comparing it to the actual GPC data. So the -- we're making this comparison based on actual GPC data from the seven-year dog study, and we've got the -- plus or minus the range of the data on top of

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the 61,000 mass units, and we're comparing that to a computed molecular weight that you would get from a combination of having a crust and a core that's not degraded. So we're doing that calculation. We're seeing what the change in the molecular weight would be, and then we're comparing it against the actual molecular weight data from the dog study.
Q Okay, so --
MR. HUTCHINSON: Dan, excuse me, let me give you just a heads-up. We're coming close to seven hours.
MR. THORNBURGH: Yeah, no, I'm almost done, but this is an important --
MR. HUTCHINSON: Okay.
MR. THORNBURGH: -- issue.
THE WITNESS: Okay.
MR. HUTCHINSON: I'm just going to tell you, though, that I am going to call the deposition at seven hours, so we're getting close --
Q (By Mr. Thornburgh) But you don't know --
MR. HUTCHINSON: -- as a courtesy to you.
Q (By Mr. Thornburgh) You don't know what the

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crack depths were in the dog study, right? Wouldn't the proper procedure or analysis be to analyze the depth of the cracks on the dog study if you're using the GPC data from the dog study?
MR. HUTCHINSON: Object to form. Compound.
THE WITNESS: Well, you can -- that would actually wind up being more favorable. Because if you look at Dr. Iakovlev's relationship that he's developed between time and crust thickness, it goes -- gets larger as a function of time. And I believe off of memory, he plots something in the seven-year mark that might be on the order of 6 or 7 microns.
So I'm actually being generous with my computation here. If I were to actually use that data, I would look worse, the computation would look worse in terms of showing that, yes, I can discern with molecular weight, even though it's a bulk analysis, if I have a crust that that's thick.
Q (By Mr. Thornburgh) Okay. And then you are

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using just one data point from the Bellew explant for the nano thermal analysis?
A I am not. If you go back and read Bellew, you'll see that he sampled -- just let me finish -- he sampled a number of different locations, he gets a range of 121 to 127 C in his data, and we've basically taken the nominal average of that.
Q But those were different treated specimens, right, so some specimens were treated -- weren't treated at all with any reagents, some were treated with sodium hypochlorite, and so there was a big change in the drop of the thermal melt point from a, you know, nontreated mesh sample versus a sample treated with sodium hypochlorite?
A Okay, let's break --
MR. HUTCHINSON: Objection, compound.
THE WITNESS: Let's break that down. If that's true -- I haven't had a chance to go back and verify that -- if that's true, the range of the data that I just cited to you is accurate, 121 to 127, regardless of treatment, nontreatment, et cetera, from the Bellew mesh. It's a 6-degree window. I've used the nominal average. There's not a lot

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of variation there. This computation is solid based on the estimates that we've used from your expert reports.

Q (By Mr. Thornburgh) The analysis that you did of the histopathology of -- you wanted to prove a couple theories wrong of Dr. Iakovlev's, I think is what you stated earlier?

A Yes.

Q And you -- so you had some -- you purposely degraded some samples of pristine TVT devices, right?

A Of pieces of mesh, of pieces of TVT mesh, yes, we did.

Q Okay. And you used ultraviolet radiation?

A We did, we used a QUV chamber.

Q What was the depth of the cracked surface layer of that purposely degraded polypropylene suture?

A I would estimate it to be 20 to 25 microns. I'm using Figure 15 in that report as a reference.

MR. HUTCHINSON: Dan, two or three more minutes now.

MR. THORNBURGH: Come on.

MR. HUTCHINSON: You had seven hours.

MR. THORNBURGH: How long have we been on the record?

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THE VIDEOGRAPHER: I have to add it up. Sorry.

(Discussion off the written record.)

THE VIDEOGRAPHER: Six hours and forty minutes.

MR. THORNBURGH: Twenty minutes.

Q (By Mr. Thornburgh) All right, so you took the --

MR. HUTCHINSON: We started at 9:30.

Q -- TVT pristine samples. You did ultraviolet radiation. And then what did you do?

A We also -- we also did another set of samples in parallel when we chemically oxidized it.

Q Yep. And then after you did chemical oxidation and ultraviolet radiation oxidation, what did you do with those samples?

A We placed those samples in an embedding media, both paraffin and a resin, to basically create a solid specimen that we could then microtome, and then those samples were microtomed to create thin specimens -- that's very common in histology, as I've learned -- to place those on glass slides. And then they were subsequently stained per the protocol that we've listed inside the report.

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Q Who actually did the staining of these slides?

A That would be the firm Histion, H-I-S-T-I-O-N, in Everett, Washington.

Q Why did you refer it to Histion in Everett, Washington?

A We wanted to use a lab that has core competencies in histological staining, and this is something that they've been doing for, I believe, 20 or 25 years.

Q And so the images of the ultraviolet radiation staining are on page 15; is that correct?

A For the QUV -- for the UV oxidized mesh, correct.

Q Why are the images so blurry?

A Well, it's because -- let me explain to you, these samples are very, very thin. They're microtomed samples, and you have to remember that the original sample is a piece of mesh that is embedded in paraffin or resin so you could do the microtoming process. There are no guarantees, as we talked about in the report, that as I slice a fiber that's embedded, that I'm going to get a perfect circle for a cross-section, because the mesh itself might be slightly misaligned

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with the microtome blade, and there's nothing you can do about that. That's the nature of the process.

And because of that, the specimen may not ultimately lie perfectly flat on the glass slide, and if it's not perfectly flat at these -- I shouldn't say perfectly flat. The specimen itself might have a bias to it, the cut might be biased. And because of that, you will have different fields of view that come into focus a little bit differently from neighboring sections. So it's just -- it's the nature of trying to look at microtome specimens in this manner at higher magnifications.

Q And the staining and the microphotographs were all done at a different lab?

A These were all done at Histion, correct.

Q Okay. And you sent the mesh specimens to Histion after you had oxidized them or degraded them through ultraviolet radiation?

A That's correct.

Q And how many samples did they stain?

A Oh, several. I'd have to look at the raw data.

Q You only have a picture of one, is that right, or two?

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A We've got -- we have one represented here, No. 9, on Figure 9, and then we have the --
Q Figure 11?
A -- exemplar as Figure 11.
Q That's unoxidized, right?
A That is. That's unoxidized. And then chemically oxidized is Figures 6 and 7.
Q How many -- how many images, photo micrographs were taken of the QUV-treated mesh samples?
A I don't recall. We'd have to look at the raw images that are on the thumb drive I gave you.
Q Who picked out the samples to -- or the microphotographs to use in this report?
A I did.
MR. THORNBURGH: I have one hour and twenty minutes left on the record. Thanks.
MR. HUTCHINSON: Huh? That ain't right. We're off the record real quick.
THE VIDEOGRAPHER: Off the video?
MR. HUTCHINSON: That's not -- yes. That's not right. We started --
THE VIDEOGRAPHER: We are now going off the video record. The time is currently 5:43 p.m.

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(Off the record.)
THE VIDEOGRAPHER: We are now back on the video record. The time is currently 5:44 p.m.
Q (By Mr. Thornburgh) Who performed the process of doing the QUV degradation?
A Dr. Benight. Dr. Benight, at my direction.
Q And how did she determine to stop the QUV process?
A It's pretty straightforward. If you look at the micrographs on Figure 2, we saw clear evidence of cracking on the outside surface. And knowing that those are pristine fibers to begin with, they're in a QUV environment, when you see this degree of cracking, it was a -- it was a visual observation that said, okay, we've definitely degraded it, it's done.
Q But if you understood that the average crack depth is 4 microns, according to your analysis that you did in the prior section a moment ago, why would you stop the degradation process at 20 microns?
MR. HUTCHINSON: Object to form.
THE WITNESS: Look, all I'm trying to do -- let's not overcomplicate this. All I'm trying to do is take a Prolene specimen,

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knowingly degrade it, and see if it stains. The thickness is irrelevant in this -- in this testing, in this experimental approach. We're just trying to say if I have oxidized Prolene, will it stain, and the answer is no.
Q (By Mr. Thornburgh) Let me just try to -- so how do you -- how did you calculate or estimate a 20-micron crack in this specimen?
A We didn't. We didn't. It was just a measurement from looking at micrograph number -- or Figure 9. If you look at the cracks that are penetrating inside the fiber and you use the scale bar to the right, I've estimated it about 20 to 25 microns in depth. And again, that depth is really irrelevant here. It's not -- it's not part of the study.
Q Okay, so you're measuring from the outside of this image to the core? Is that the core right there?
A I wouldn't call it the core. I'm just trying to estimate -- you asked me how deep the cracks were, at least that's what I thought you did, and I just looked at these figures and I used the scale bar; and seeing the cracks that radiate inward, I'm saying that they're about 20 to 25 microns in depth.
Q Have you -- you've looked at Dr. Iakovlev's

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report, right?
A I have.
Q And --
A I'm sorry.
Q -- you would agree with me that the --
MR. HUTCHINSON: Hey, guys, y'all are talking over each other.
Q (By Mr. Thornburgh) Okay. You've looked at Dr. Iakovlev's report?
A I just wanted to ask a clarifying question. For the consolidated cases?
Q Yeah, sure.
A I have.
Q And you've looked at his micrograph images, right?
A I have.
Q And why is the magnification of the pictures that you have in your report much lower than Dr. Iakovlev's images?
A Well, I think it goes back to what we just talked about. We had seen that the amount of cracking was around 20 to 25. We know that that region, because the cracks exist, is oxidized and felt it was in our best interests to be able to show that swath of

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material that has the cracks in it in these micrographs. So we were just kind of showing the region that's clearly been oxidized by the presence of crack.

Q If you look at Figure 2, which is the SEM image of the ultraviolet degraded specimen, you can see the big chunks and -- of the mesh peeling up from the surface -- I mean from the core, right?

MR. HUTCHINSON: Object to form.

THE WITNESS: You can see some peeling up, correct.

Q (By Mr. Thornburgh) Why can't I see any peeling on the image in Figure 9?

A Because you're looking at the length of the fiber here in Figure --

Q I'm sorry, Figure 9.

A Sorry. In Figure 9, you're looking at a cross-section. So it just so happens to be that in this particular cross-section that was -- that was performed by microtoming, we didn't happen to catch that region that had some curling to it.

Q Did you -- in any of your micrographs, did you catch any images of the peeling of the surface layer?

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A Oh, I don't recall.

Q Can you see a skin-core difference, in other words, can you see a skin of degraded polypropylene and a core of undergraded polypropylene in your other images?

MR. HUTCHINSON: Object to form.

Q (By Mr. Thornburgh) Or is that what we're seeing here?

A You can see it -- you can see it here. I --

MR. HUTCHINSON: Object to form.

THE WITNESS: I appreciate it's a little but difficult to see, but basically where the cracks end, the tips of the cracks, if you will, that are emanating inward, that region would be the degraded region, and then everything inboard of where those cracks stop would arguably be the so-called core.

Q (By Mr. Thornburgh) So you agree that this degraded polypropylene has a degraded core or degraded bark, right?

A I agree that the outer layer of this fiber has suffered from UV degradation.

Q Did you use any automated stainer?

A We did.

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Q What was the automated stainer?

A It would -- it would be in the -- it would be in the files of the notes.

Q Is it --

A I don't have the name of it.

Q Is this what you were discussing earlier, that it was impossible to hold cross-sectioned mesh on the slides in a vertical position?

A Repeat that. I'm sorry.

Q Would you agree that it's impossible to hold the cross-sectioned mesh on slides in the vertical position using the automated stainer?

A No, I wouldn't agree with it. That's exactly what we did. We mounted the microtomed specimens onto the slides. Some of them will fall off, and those are just -- those are just not used. The ones that survive the staining process are the ones that we then imaged.

Q So some of the mesh specimens fell off of the -- of the stainer?

A Correct. And that will happen and that's why you make multiple samples, and the ones that survive the whole process are the ones that you then utilize for microscopy.

Q Did you use vertical?

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A Yes, vertical orientation.

Q Okay. Do you understand that the only way to cross -- to cross -- to stain a cross-sectioned mesh is to do it on a horizontal tray?

A I don't agree with that.

Q You didn't actually perform the staining?

A No, but I witnessed it.

Q Who up there -- was it -- was it Benight?

A Mrs. -- yeah, Dr. Benight.

Q So Benight did it and she did it on the vertical position, right?

A Correct. And for the record, we know the staining process works because that's why we used the positive control that you see on page 11. Same orientation, same staining bath, same staining process.

Q Did you do any manual staining?

A We did not.

Q How did you wash the sections?

A It says it's in the -- it's right in the protocol. I defer to pages 20 and 21. Twenty is the alcohol rinsing and dehydration before you mount it in paraffin or before you mount it in the resin. And then page 21 -- excuse me. This is all just for paraffin. And then page 21 has the sequence of the various washes

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and baths and the associated times.
Q And if you look at Figure 8, you have another Prolene mesh that was chemically oxidized using the Guelcher protocol?
A Yes.
Q Why is that image so blurry?
A It's the -- it's the same answer. It's the fact that you're trying to take a micrograph of a cylinder and your field of view is very limited to focus on. It's not an SEM image where you have the benefit of depth of field. This is with light -- with a light microscope and you had just don't have that same depth of field.
Q You saw cracking in SEM, right --
A For the --
Q -- obviously?
A For the QUV sample, we did, correct.
Q Okay. If you saw cracking in SEM, why can't you see it in the light microscopy?
A We did not see any cracking in -- are we talking about the chemically stained sample?
Q Yeah.
A We did not see any surface cracking on the chemically stained specimen.

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Q Okay. And on the --
A Sorry, in the chemically oxidized specimen.
Q On the ultraviolet radiation degraded mesh, we see cracking in the SEM, but we don't see it in the light microscopy, or is that where you're saying those are cracks but you just -- they're just blurred?
A No, I'm not saying that. I'm saying that with the chemically oxidized specimen, as we viewed them in SEM, we did not see any surface cracking that was similar to what we saw with the QUV samples.
Q This is your light microscopy on the ultraviolet radiated mesh, right?
A Correct.
Q And --
MR. HUTCHINSON: Dan, so the record is clear, you're talking --
MR. THORNBURGH: Figure 9.
MR. HUTCHINSON: Okay.
THE WITNESS: Yeah, right-hand side Figure 9 he's pointing to.
Q (By Mr. Thornburgh) Figure 9 is the -- is the light microscopy, right?
A It's -- yes, with polarized light, correct, but it's light microscopy. And that's the difference

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between those two images in Figure 9. One is with traditional light microscopy; one is using polarized light.
Q Do you agree that the tangentiality of sectioning can cause an overlap between nondegraded and degraded layers?
A Can you describe what you mean by "tangentiality"?
Q No.
A I'm sorry, then I'm going to have a hard time answering that.
Q In the QUV-treated mesh specimens, when you did the staining, did you put it in some sort of protein first?
A No, we did not.
Q So you just -- you have the material, you put it on a slide, I assume?
A Ultimately, after you embed it.
Q After you embed it and then slice it?
A And slice it and then it goes on the slide, correct.
Q And then you stain it without any protein or anything on the slide; is that correct?
A That is correct, there is no protein involved

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in this experiment whatsoever.
Q So no protein could be absorbed into the degraded bark or the degraded layer, right?
A Correct.
Q If some protein was absorbed into the cracks in the mesh and then you used H&E staining, those stains could penetrate where the protein would be located; is that correct?
A Correct, but that would be inconsistent with the micrographs I have seen from Dr. Iakovlev.
Q In what way?
A There's plenty of regions where there's no local crack for that penetration that you just hypothetically described to stain a particular region. There's plenty of regions within his micrographs that are just pure crust with no crack and they stain.
Q One of your -- one of your theories is that proteins get absorbed into the polymer cracks, right?
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) Underneath the surface or within the surface, which causes the plasticization?
A There are -- there's a potential for proteins and other molecules with carbonyl functionality to be absorbed by the material.

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Q Okay.
A Yes.
Q So -- but you're saying that Dr. Iakovlev's H&E staining and analysis of explanted mesh material is incorrect to demonstrate that the outer layer is degraded bark, right?
A He is -- let's be clear on this. He is using his staining technique to unequivocally say the material is degraded from oxidation. And this study completely contradicts and by no way supports that theory. If you have an oxidized material, polypropylene -- or, excuse me, Prolene, it does not stain. He hasn't talked about any secondary mechanism of staining. He's unequivocally on the record saying the degraded oxidized Prolene stains, and it does not.
Q Do you know how long it takes for the -- how long does it take for degradation, outer degradation, skin, of a Prolene fiber to degrade to a thickness that's detectable by light microscopy? Let me ask that question again.
A Okay.
Q Do you know how long it would take -- at what depth of the degraded bark can the light microscopy detect the degraded layer of the protein fibers?

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A I'm sorry, I'm lost in the question. Maybe we can do that again.
Q Sure. The only staining of the mesh would be at 20 microns, is that right, 20 microns?
A Not at the 20-micron level. I mean, we know -- just basic polymer science tells us that if I've got QUV lights bombarding the specimen to degrade it like we see here, that the material that's at the very, very, very outermost layer is probably going to suffer more oxidation, more degradation than stuff that's more towards the fiber core. So there will be a -- there's probably a gradient of UV degradation across that crack thickness that we see. I don't know if that answers your question, but --
Q Do you remember seeing an animal -- an internal Ethicon study that said the way to definitively determine whether or not the outer layer of the explanted Prolene fibers is degradation is to do intentional oxidation of pristine samples to see if there's a skin-core morphology that's created?
A Yeah, I recall some -- maybe Dr. Moy. I recall that somewhere. Sure.
(Discussion off the written record.)
(Exhibit 19 marked for identification.)

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Q (By Mr. Thornburgh) Let me hand you what I've marked as Exhibit 19. Have you seen this document before?
A I have.
Q This is from 1984?
A It is.
Q And in this report, they talk about different potential causes of the degraded outer layer of the fibers or the morphological changes in the fibers, right?
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) So it's dated November 5th, 1984. It's titled "Prolene Microcracking," right?
A Right. You just gave a summary of the document. I'm just trying to see if I agree with your summary. Why don't we just say this: The document speaks for itself in terms of what it purports to say.
Q The document summarizes experimental findings related to microcracking and related to Prolene sutures, right?
A Correct.
Q The cracks are predominantly transverse; do you see that?

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A I do.
Q No. 2, "Severity (depth and density) and location of the cracks are nonuniformly distributed along the suture lengths and do not correlate obviously with areas of high stress." See that?
A I do.
Q And then No. 3, "The severe" -- "In severe cases, the cracks lead to the production of a separated layer of seemingly uniform thickness and a relatively clean under surface." No. 4, "Also in severe cases, secondary longitudinally cracks give rise to brick-like structures."
A Correct. Just all visual observations of the cracked outer layer.
Q And if you look at the "Laboratory Studies, Experimental and Results," it says, "The following experiments were carried out to test whether microcracking results from physical (environmental stress cracking) or chemical (oxidation) degradation and whether the discrete thickness of the crack layer arises from natural separation point in the fiber (skin-core morphology)." Did I read that correctly?
A You did.
Q It says environmental stresses cracking,

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talks about the process of environmental stress cracking, says that polypropylene fibers have been shown to develop crazes at elongations as low as 5 percent. It talks about the hypothesis that long-term exposure to a sensitizing agent in vivo may result in environmental stress cracking and formation of microcracks, right?

A That's what it says. Let's -- while we're here, let's just hit this. There's absolutely no evidence to suggest that ESC is taking place in these fibers.

Q Well, a drop in the DSC --

MR. HUTCHINSON: ESC.

Q -- a drop in the DSC results, right, would be indication of amorphous zones that would make a polypropylene suture susceptible to environmental stress cracking, right?

MR. HUTCHINSON: Object to form.

THE WITNESS: Environmental stress cracking is a physical phenomenon. It is coupled also with embrittlement. We don't see any embrittlement with these fibers whatsoever. There is no evidence of ESC.

Q (By Mr. Thornburgh) "Oxidation: A great

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body of literature exists regarding oxidative degradation of polypropylene." So it talks about the mechanism of oxidation. We don't have to go through all that, right?

A Fine.

Q And then see the "Skin-core Morphology" section?

A I do.

Q It says, "If there is no significant difference between the skin region of the fiber, relative to the core, then the thickness of the layer depends only on the extent of whatever reaction is taking place. Skin-core morphologies have been observed in many different types of polymeric fibers. The skin generally results from a temperature gradient experienced by the fiber across the fiber diameter during the quenching step of extrusion. Such a skin layer is generally higher in orientation than the core due to the higher efficiency of heat conduction on the surface. Skin-core morphologies are also generally found in fibers at low to medium degrees of orientation." Did I read that correctly?

A You did. And somewhere in the universe of Ethicon documents, Ethicon explored the potential for

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skin-core morphology and discredited it.

Q Well, let's -- we're looking, maybe, at the document. I don't know.

A We may be.

Q Let's take a look at it. See the thermo-optical analysis? They analyzed mesh explants usually in thermo-optical analysis, correct? What is thermo-optical analysis; do you know?

A I'm sorry, I'm trying to keep up with you. Where are you?

Q I'm on page ETH.MESH.455, page 4.

A Yeah, I'm on the same page. Just tell me which --

Q "Thermo-optical Analysis."

A What paragraph are you on? The bottom paragraph?

Q Yep, Figure 7. They did some -- they did some melt-point analysis, right?

A Yes, they're visually observing melting of the polymer or the melting of the sample, I should say. So they put the -- they put the -- whatever sample they're going to analyze on a hot stage, typically it's done with a microscope so you can see it, and you're actually visually watching melting as the stage heats

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up. Is that what you're asking?

Q Yeah. And so they do that and they see upon heating at 150 degrees Celsius, the fiber is taken to its softening point, and contraction along the fiber axis leads to an increase in the diameter of the crack, layer peels off the fiber cleanly. So they're talking about a cracked layer peeling off of the core --

MR. HUTCHINSON: Object to form.

Q -- at different temperatures, so it's not melting, it's not -- the cracked layer isn't melting with the core is what they're suggesting here, right?

MR. HUTCHINSON: Object to form.

THE WITNESS: What I'm reading here is that they start to see the fiber melting at 150, and it looks like it ultimately reaches its final melting point of 165.

Q (By Mr. Thornburgh) Right, but the cracked layer maintains its form; that's what it says?

A Correct. So --

Q And so they say the --

A Hold on. Okay, go ahead.

Q "The layer is crosslinked polymer or it is predominantly proteinaceous in nature. If the crack layer is oxidized degradation" -- "degraded

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polypropylene, the molecular weight should be lowered, leading to an increase [sic] in melting point --
A Decrease.
Q Sorry. "If the crack layer is oxidized/degraded polypropylene, the molecular weight should be lowered, leading to a decrease in melting point of the layer rather than a higher one."
A I agree. I agree with that.
Q Well, but here they're talking about how the -- an explanted mesh material or Prolene material undergoes thermo-optical analysis, and they start to heat it up and it actually -- the thermal melting point actually rises when protein is attached to the surface?
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) Because you had indicated previously that the melt points are mistaken -- being misunderstood because they're actually lowered because of the protein contamination around the fibers.
A We're saying -- we're saying two different things. When you're sampling a fiber surface that's been plasticized, like we know happened with Jordi's work, you will see a suppression in melt temperature. That has nothing to do with existence of proteins on

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the surface. I'm talking about plasticized Prolene.
This document further confirms what we've been saying all along, which is the crust which they've isolated here with their thermo-optical analysis, melts at a higher temperature than the Prolene material.
Q In this -- in this one study of this one explant, that's what they're -- that's what they're observing?
A Correct, that is correct, in this study.
Q And --
A And it contradicts the oxidation and degradation theory a hundred percent.
Q Look, the melt point actually increased because of the protein that was encasing this particular explant, right?
MR. HUTCHINSON: Is that a question, Dan?
MR. THORNBURGH: Yeah.
MR. HUTCHINSON: Excuse me.
Q (By Mr. Thornburgh) They're observing an increase in melt point in this explant, right?
A They are.
Q Not a decrease in melt point, right?
A Correct.

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Q And we've got to change the tape, but real quick, you looked at Dr. Jordi's analysis and you observed a decrease -- he observed a decrease in the thermal analysis or the melt point of the Prolene samples he analyzed, right?
A Correct.
Q Not an increase?
A Correct.
MR. THORNBURGH: Okay.
THE VIDEOGRAPHER: We are now -- we are now going off the video record. The time is currently 6:13 p.m. This is the end of Tape No. 5.
(Recess taken.)
THE VIDEOGRAPHER: We are now back on the video record with Tape No. 6. The time is currently 6:20 p.m.
Q (By Mr. Thornburgh) Doctor, we're talking about Exhibit No. 19, and this is the November 5th, 1984 memo. And just to sort of summarize what we're looking at, we're trying to determine what the outer layer is that has been observed on explanted Prolene sutures, correct?
A That's what we've been talking about,

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correct.
Q And they're hypothesizing, they're saying maybe, you know, ESC is a potential cause for degradation, oxidation is a potential cause, protein or biologic material is a potential cause, skin-core morphology is a potential explanation, in other words, because of the spinning process for -- during the extrusion process of the mesh and the cooling process, that the outer layer is cooled quicker and creates a skin that has more amorphous regions than the crystallinity -- the more crystalline core, right?
A Sure, that's a decent summary.
Q And there's a recommendation made to try to figure it out once and for all, try to determine and answer the question once and for all, the recommendation by Peter Moy is to do additional -- an additional study to either substantiate or disprove the hypothesis that the outer layer is biologic in origin, and that study would be to do similar transmission electron --
MR. HUTCHINSON: Microscopy.
Q -- microscopy examinations on known oxidized Prolene samples to determine whether such a different skin-core morphology could be generated by oxidation,

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right?
MR. HUTCHINSON: Object to form.
THE WITNESS: That's what it says.
Q (By Mr. Thornburgh) And did you, in your review of the internal Ethicon documents, ever find any scanning electron microscopy or transmission electron microscopy to determine -- which looked at intentionally oxidized Prolene samples?
A We know that they have actually analyzed oxidized polypropylene samples. We talked about that earlier, intentionally oxidized polypropylene samples. Whether there were micrographs that accompanied that work, I just don't recall.
Q Yeah, we looked at that earlier. They didn't have -- that was 1983. They didn't do it then. Right here in 1984, they're saying, "We should intentionally oxidize some Prolene sutures and then do scanning electron microscopy or some other analysis to determine if there's a skin-core phenomenon going on," right?
A That's what he --
MR. HUTCHINSON: Object to form.
THE WITNESS: That's what he says.
Q (By Mr. Thornburgh) And, in fact, you did intentional oxidation using radiation and found a

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skin-core morphology with an outer layer of polypropylene surface being degraded, right?
MR. HUTCHINSON: Object to form.
Mischaracterizes the tests and the results.
Q (By Mr. Thornburgh) We talked about it earlier. I asked you, "Now, Doctor, there's a skin-core morphology here," and you said, "Yes," and I said, "The outer layer is degraded and the core has remained nondegraded," and you said, "Yes," right?
A I said there was peeling observed in that one micrograph. You said there was a skin-core morphology.
Q I -- well, the record will speak for itself --
A Okay.
Q -- but in any event, the scientists in 1984 were suggesting that a study like yours be done, and you did it and you confirmed what they -- their findings?
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) Or their -- I mean, here's what the language is, right, the language is, "An additional study to either substantiate or disprove this hypothesis would be to do similar transmission electron microscopy examinations on known oxidized

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Prolene samples to determine whether such a different skin-core morphology could be generated by oxidation."
You oxidized the Prolene samples using ultraviolet radiation, right?
A Correct.
Q And the outer layer cracked and some of it was peeling away?
A About 20 microns, 25 microns of cracking, correct.
Q And while the skin was cracking, the core remained intact and unaffected, right?
A Let's look at -- let's be clear about this. First of all, it's not clear to me why he thinks that that particular study would confirm or deny his hypothesis. So that's -- let's leave that here. That's something you're going to have to ask Dr. Moy. I don't understand why that particular study would be necessary to confirm his hypothesis or reject it. But if you look at my micrographs on Figure 9, you can see the cracked layer. But other than the cracks being present, I certainly don't see a discernible skin-core morphology developing.
Q Look at Exhibit 5 -- or Figure 5, which is your scanning electron microscopy.

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A We can, but I just told you I'm referencing Figure 9, which is a cross-section, which is a much better indication of what's happening inside the material than something looking on the outside in. And what I'm telling you is that, yes, we can see definitive cracks here, but there's no evidence of a, quote/unquote, skin-core morphology that's setting up. I've got a cracked outer layer and the crack stopped. I don't necessarily characterize that as skin-core.
And secondly, we have to realize what the data we have is already telling us. We know, we've already confirmed as an original hypothesis, we know based on Iak's staining work and our lack of staining in our work that the crust contains a biological component. It's indisputable. The staining took place with Iak. The staining did not take place in our deliberately oxidized samples.
Q Can you see any of the blue granules on the -- in the degraded bark or the degraded layer of your microphotograph?
A Sure, I can see the colorants. I can see the colorants, sure.
Q In Dr. Iakovlev's studies, in his histopathology, in the degraded outer layer, where it's

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clearly cracked, you can see those blue granules within the cracked layer, right?
A We can. And we've shown that that can be an artifact of the light polarization with the microscopy. If you look at Figure 11B -- and I don't -- it doesn't matter that this is an unoxidized Prolene sample. We're just talking about artifacts from the microscopy techniques. We'll actually be able to show that you can get something that looks like a bark with this gradient of colorants in a sample that's not even oxidized. This is exemplar pristine mesh and we can actually -- playing with the polarization of the light, we can introduce that same mechanism or that same -- those same features, if you will.
And I know that that might be difficult to understand, so I'm going to help -- I'm going to help you understand it a bit more. If we were to put a second layer out here (indicating), and I'm going to trace it with my pen, and let's just say this had all stained purple like we see with Iak.
Q Why do you keep on calling him Iak?
A That's just -- I think that's the one-syllable nickname that I've coined him.
Q I think that's disrespectful.

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A Sure. I apologize. Dr. Iakovlev.
Q How many times have you been published in peer-reviewed journals concerning the degradation of polypropylene fibers?
A None.
Q You've been doing it for the last 5 or 10 years, correct?
MR. HUTCHINSON: Hey, guys, stop. Stop.
MR. THORNBURGH: Don't call my witness Iak.
MR. HUTCHINSON: Hey, I'm telling you to stop. Do you understand?
MR. THORNBURGH: No, listen, he doesn't have to -- he doesn't have to be rude and disrespectful.
MR. HUTCHINSON: Hey, guys, I'm telling everybody to stop. What I'm going to tell you is if there's a question pending, I need you to answer the question.
Dan, I don't know if you had a question pending or not, but if you could, ask the question.
Q (By Mr. Thornburgh) Well, my -- let's just take it to here. If we look at Figure 9, which we know

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is oxidized polypropylene, right, you intentionally oxidized it, right --
A We did.
Q -- and in the outer layer of the cracked surface are blue granules, right?
A Correct.
Q And those blue granules are polypropylene -- or are the dyes within the polypropylene, right?
A Correct, but none of that region is stained.
Q But I can see the blue granules in the degraded layer. That's all -- that's my only point. I can see blue --
A Of course you can.
Q -- granules --
A Of course you can.
Q -- in the stained layer, right?
MR. HUTCHINSON: Guys, one at a time. Dan, would you restate your question.
MR. THORNBURGH: Yeah.
Q (By Mr. Thornburgh) In the intentionally oxidized polypropylene sample that you analyzed, there are blue granules within the degraded polypropylene layer, right?
A Yes, of course.

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Q And why are they there?
A Because they were there with the native fiber. They come in with the fiber.
Q Because the degraded -- because the degraded layer is polypropylene, right?
A Yes. That's what we've been saying all along. We've deliberately degraded this specimen under QUV conditions; and, of course, the polypropylene and the colorant that's on the outside of the fiber has seen the QUV exposure. The polypropylene degrades; but, I mean, the copper pigment particles still stay there.
Q Right. And that's similar to the photomicrographs that you've seen in Dr. Iakovlev's expert reports with blue granules, which are part of the polypropylene, which are in the polypropylene material in the outer degraded layer of the explant, right?
A I have and I --
MR. HUTCHINSON: Object to form.
THE WITNESS: I have. And I'm telling you two things, that that is an artifact of his light polarization. We've proven it here if you read through page 16 and 17 and look

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at Figure 11. And in addition to that, if you look closely at all of his micrographs with the so-called particles in them, in the crust layer, you see a true gradient across the thickness.

And so if you get back to the diagram that I was just trying to sketch out with you, if you had a true crust out here -- we have false bark here in Figure B. If I sketch out some true bark or crust to the outside of that and if you can visualize this all being purple or violet, you would actually get the same exact image that Iak has in his pictures, in his micrographs.

MR. THORNBURGH: His name is Dr. Iakovlev.

THE WITNESS: I'm sorry. It's late in the day. Dr. Iakovlev. I apologize. I'm not intentionally doing that.

(Discussion off the written record.)

(Exhibit 21 marked for identification.)

Q (By Mr. Thornburgh) I'm handing you Exhibit No. 21, which is a memo from Dr. Lunn, March 23rd, 1983. Have you seen this document before? You have.

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It's in your -- on your reliance list at least.

A My answer is yes. I'm just refreshing my memory. Okay.

Q And this is another memo concerning the Prolene microcracks, right?

A It is.

Q And do you recall this report or this set of reports?

A I recall reading these documents at some point, yes.

Q Do you recall that Ethicon back in 1983 did the same histopathology or pathological analysis as has been done by Dr. Iakovlev of explanted Prolene sutures? It says right there on the very first paragraph, "The slides were reviewed by light microscopy using polarized light to help identify the cracking." Do you see that?

A I do.

Q And these were explants from human specimens, right?

A Correct.

Q Okay. And then if you turn the page just to the next -- the very next page in this exhibit, you'll see photomicrographs, which are poor images, but you

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can seem them here, right?

A I do.

MR. THORNBURGH: By the way, can we get the original copies of these or better copies of the original three 35-millimeter slides if they're available? I'll send you an email.

Q (By Mr. Thornburgh) Do you see the arrows that are pointing to the outer degraded bark?

A I see arrows pointing to what appears to be a -- some sort of cylindrical crust layer, correct.

Q Turn the page. This is an analysis of another Prolene graft explant, correct? And the finding was that the 5-0 Prolene from Specimen 2 were carefully removed from the graft and tested for breaking strength, BSE, and the results were 54 percent breaking strength maintaining when measured against similar size control?

A I do.

Q Okay. So in this explant, the -- unlike what you discussed in the dog study, there was a decrease, a significant decrease in the breaking strength, right?

A Sure. Two things on that if it's a question. One is, it's one data point; and two is, it's not uncommon, if you get plasticization, to get some

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reduction in tensile strength. It's not that -- it's uncommon to get a reduction in tensile strength.

Q Okay. So this is a significant reduction in tensile strength, right?

A Yeah, but it's not -- it's not ductility. We haven't seen -- I haven't seen anyone complaining that these fibers are breaking in vivo, okay? So the allegations that I've heard is that this material embrittles and this material gets stiff. Those are not tensile strength properties.

Q Yeah, but you are using the dog study to suggest that the Prolene fibers don't lose significant tensile strength, but when you look at explants from human -- human explants of Prolene sutures, you see significant reduction in tensile strength, correct?

A Yep.

MR. HUTCHINSON: Excuse me.

THE WITNESS: Yep.

MR. HUTCHINSON: Excuse me. Dan, were you finished with your question?

MR. THORNBURGH: Yeah.

MR. HUTCHINSON: Object to form.

Q (By Mr. Thornburgh) That's what we're seeing here, right?

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MR. HUTCHINSON: Object to form.
THE WITNESS: We're seeing one data point that has 54 percent either strength or reduction in strength. And what I'm saying is that the key physical properties that are being maintained, if not being improved, are the flexibility and the ductility. The tensile strength is still fine, it's still plenty fine. Of course, you can supplement that with the seven-year dog study, but this data point does not confirm that that material is oxidizing.
And for all we know, there could have been some sort of surface flaw or something, some artifact on the outside of the specimen that actually causes it to break a bit prematurely. That is not uncommon as well. So, you know, you've got to take that data point with a grain of salt. And I'm not concerned about it even if it is accurate without a flaw.
Q (By Mr. Thornburgh) We're going to look at some more data points.
A Okay.

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Q Don't worry. See the histological evaluation on the next page? There was -- the fibers were infiltrated with macrophages and giant cells and fibroblasts, and cracking of the suture surface was also evident in longitudinal sections of Prolene located near the graft fibers. Cracking appeared along only one edge of the Prolene and was especially prominent when viewed with polarized light.
A That's what it says.
Q "Measured against a 5-0 Prolene control, this segment had 54 percent strength remaining. Light microscopy evaluation of this strand revealed surface cracking identical to Sample No. 1," right?
A That's what it says.
Q If you go to the document dated March 5th -- March 25th, 1983. March 25th, 1983.
MR. HUTCHINSON: And this is all within Exhibit 21?
MR. THORNBURGH: Examination of -- yep. Examination of 5-0 and 6-0 cardiovascular Prolene sutures.
THE WITNESS: Yep, here it is.
Q (By Mr. Thornburgh) There were nine samples that were submitted. Three of them had been stored in

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formalin from the time of removal from the patient; the others had been allowed to dry. Do you see that?
A I do.
Q So the others weren't stored in formalin at all, correct?
A I don't think we can say that for sure based on the way that's written.
Q It says three of the nine had been stored in formalin from the time of removal from the patient. The others all -- had all been allowed to dry.
A Correct. It doesn't say -- it doesn't say they were never stored in formalin and were allowed to dry. It just says that they were allowed to dry.
Q Well, "The dry samples were examined dry (in air). The wet samples were examined mounted in the formalin in which they were stored." Right? And you see that they are -- the observations show some cracks on some of these nine explants?
A Correct.
Q The general observations and conclusions on the next page was that, "Sutures kept in the wet state do not exhibit cracks. Upon drying, cracks appear. This was actually observed happening by drying the six-year wet on the microscope stage. It is obvious

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that the severity of the cracks is related to the implantation time." Do you see that?
A That's what it says.
Q Now, you've seen the dog study where cracks were observed on both the dry and undry samples, right?
A Yes, I've seen -- yes, we've seen cracks on many of the seven-year dog study samples.
Q And the researchers in the dog study said unequivocally that sample preparation did not cause the cracking, right? Do you recall seeing that in the five-year study?
A I don't recall. I'm not disputing that that's what was written.
Q You're not going to offer -- you're offering opinions that cracking -- or drying or analyzing wet samples somehow creates artifact?
A I'll say I think it's noteworthy that on several occasions, Ethicon saw cracks develop when samples dried.
Q Do you know why that was?
A Well, one theory would be if it's a formalin-fixed crust and it's allowed to dry and shrink in air, you might get cracking.
Q What's the refraction index of the media

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that's used in scanning electron microscopy or microscopy? How does that influence the ability to observe the physical characteristics on top of a suture; do you know?

MR. HUTCHINSON: Objection. Compound question.

THE WITNESS: I'm not sure what you mean by "refractive index" and with regard to SEM, so maybe you could just orient me a little bit more.

Q (By Mr. Thornburgh) Do you know what -- what is a refractive index of scanning electron microscopy?

A Refractive index is a -- is a material property. So that basically dictates how light gets diffracted and scattered when light hits a sample. It's like tensile strength of material. It's a physical material property of a material or sample. It has nothing to do with the actual microscopic equipment.

Q But my question is, the media -- the medium that's used or the solution that's used, if it's a wet sample, can impact your ability to observe the surface layer as a result of this refractive index. You've experienced that, right?

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A If you're --

MR. HUTCHINSON: Object to form.

THE WITNESS: No, I have not experienced that in SEM. I have not.

Q (By Mr. Thornburgh) If you see on May 2nd, 1984 --

A Just give me a page.

Q It's the -- it doesn't have page numbers. Somehow it didn't print with the Bates numbers.

MR. HUTCHINSON: How come this doesn't have Bates numbers on it?

MR. THORNBURGH: It just didn't print with them. I don't know.

MR. HUTCHINSON: But these are documents part of the --

MR. THORNBURGH: These are documents pulled out of Ethicon's file.

Q (By Mr. Thornburgh) May 2nd, 1984, the summary evaluation of surface cracking and tensile strengths. Do you see that 1 to 5 -- Samples 1 through 5 were received by Dr. Bellingham, Stanford University Medical Center, and had Prolene suture in residence for one to two months [sic] to four years three months postop, sizes were 3-0 and 4-0?

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A Correct. That's what it says.

Q "Subsequently, sutures were examined by light microscopy while wet and dry. Histological preparations of Prolene cross-sections in tissue were stained in phloxine." What's phloxine?

A Phloxine, I believe, is some other type of staining medium.

Q Stained in phloxine and examined for cracking. "Sample 1 through 5 showed no surface cracking in light microscopic examinations of both explanted sutures or histological sections. Sample 6 displayed severe cracking of a 3 to 4.5 micron layer as measured in histological cross-sections.

"The average breaking strength remaining for sizes 3 was 76.5 percent (range 47 to 93 percent) and for size 4.0 was 98.25 (range was 86 to 110 percent) when compared to similar size controls. Only one length of 5-0 Prolene was available for tensile strength measurements, indicating a 76 percent strength remaining for the seven-year specimen."

So you see for all of these specimens, there was a range, some of which went as low as 47 percent, right?

A Correct. For 3-0, that's correct.

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Q The "Methods" section on the next page, "Each tissue specimen was removed from the formalin solution and rinsed with distilled water. Samples remained wet. Prolene suture was carefully dissected out of the tissue specimens and kept wet in distilled water until examination could be performed."

And they were submitted to histological preparations. Do you see that?

A (No verbal response.)

Q If you turn the page, it shows the results from the tensile strength that was remaining.

MR. HUTCHINSON: Objection. Compound question.

Q (By Mr. Thornburgh) We're talking about the same -- the same explanted material. And it shows that the range was 47 to 110 percent, right?

MR. HUTCHINSON: Same objection.

THE WITNESS: Correct.

Q (By Mr. Thornburgh) Do you see where it says, "Phloxine stain had completely penetrated the cracked layer"? We're talking about section -- histological section of Sample 6, which was the severely cracked explant. "A cracked surface layer measuring 3 to 4.5 microns was seen, accounting for

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approximately 8.5 of the total cross-sectional area. This layer was birefringent when examined under polarized light microscopy. Phloxine stain had completely penetrated the cracked layer."

A Sure. If phloxine stain has an affinity for proteins, then it doesn't surprise me.

Q "Particles of blue dye were evident within the cracked layer." Do you see that?

A I do.

Q Have you seen this before today?

A I have. Just not fresh in my memory, but I definitely have.

Q "There was evidence [sic] of migration of particles from the cracked surface layer into the surrounding tissue."

You've seen that in Dr. Iakovlev's studies where you can actually see in some photomicrographs the dye pigments outside of the cracked layer, right, that's moved out of the Prolene into the tissue? Have you seen those?

A I have and I --

MR. HUTCHINSON: Object to form. Compound question.

THE WITNESS: I have and I explained to

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you that when you look at those micrographs carefully, that -- two things. He's imaged it using polarized light, and we've demonstrated that you can get a false bark appearance that will include the dyes in that appearance, in that false bark, from our work.

And in addition to that, you see a gradient of those particles across this so-called bark or crust layer. So there's -- at least there's a -- even if it's not false bark, which I believe it is, that's still unexplained to me that a large portion of that thickness is pigment free.

Q (By Mr. Thornburgh) Here we have Ethicon's internal scientist doing the same histopathology of explanted Prolene sutures as Dr. Iakovlev has done. They're seeing --

A I would not characterize it as --

Q They're seeing --

MR. HUTCHINSON: Guys, guys, excuse me. I think -- let Dan finish his question.

THE WITNESS: Sure.

Q (By Mr. Thornburgh) They're seeing that

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phloxine stain is completely penetrating the cracked layers, they're seeing particles of blue dyes in -- within the cracked layer, and there was no evidence of migration of particles from the cracked surface layer into the surrounding tissue.

Under "Discussion," it says, "In this study, it was shown that 5-0 Prolene suture in residence within a human vascular graft for seven years displayed surface cracking. The depth of the cracking in Sample No. 6 was 3 to 4.5 microns in thickness, consistent with other specimens. Additional evidence from a seven-year specimen suggests no increase in thickness of the cracked layer over time." And then just read the next sentence for me.

MR. HUTCHINSON: Object to form.

Q (By Mr. Thornburgh) "The cracked layer appeared blue in gross specimens and blue dye particles were evident in histology [sic] sections of the layer. This would indicate that the layer is dyed Prolene polymer and not an isolated protein coating on the strands." Did I read that correctly?

A You did. However, the phloxine itself could be giving a blue hue. We -- that has not been described as to what the typical observation is in

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terms of the hue that results from the phloxine stain. So -- and as a matter of fact, the way that it's worded there might even suggest that appeared blue in gross specimen and blue dye particles were evident.

Q The blue particles were seen within the cracked layer, right? I mean, I don't understand how you -- are you suggesting that these scientists for Ethicon somehow misunderstood or misinterpreted their histopathology?

MR. HUTCHINSON: Object to form.

THE WITNESS: They very well may have. We've talked about the micrograph artifacts that you can create from the -- certain microscopy techniques.

If you read my report, you also will see that I talk about smearing, okay? And smearing is nothing more than a boundary condition effect where material on the edge of the cut, if you do a microtoming, might smear back on top of itself or smear past the original specimen.

So you -- we can't rule out, based on what's ruled here, that it isn't a microscopy artifact, and we can't rule out that there

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was smearing involved.
Q (By Mr. Thornburgh) Well, these scientists certainly believed that the cracked layer, which had these blue dye -- which had the blue particles within the cracked layer, was that -- they concluded that it was the Prolene polymer that had degraded on the surface of the fiber and not isolated protein?
MR. HUTCHINSON: Object to form.
THE WITNESS: Where do you see that they say degraded?
Q (By Mr. Thornburgh) I mean, you understand what they're seeing -- or talking about here, right? Look at the histopathology microphotographs. They're analyzing these specimens, the cross-sections of the fibers, and they -- there's this crust or this bark on the outer layer.
A Correct.
Q And they're trying to determine if it's -- if it is degraded Prolene or protein. And what their analysis found or what they concluded from their analysis, which included staining and microscopy, was that the cracked layer appeared blue in gross specimens and blue dye particles were evident in the sections of the layer that -- which degraded. And so --

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A Is there a question?
Q So this would indicate, according to these researchers, that the layer is dyed Prolene polymer and not an isolated protein coating on the strands. Do you disagree with these scientists at Ethicon as well?
MR. HUTCHINSON: Object to form.
THE WITNESS: I disagree.
MR. HUTCHINSON: Compound question.
MR. THORNBURGH: Let me ask a better question.
Q (By Mr. Thornburgh) You understand that their --
MR. HUTCHINSON: Is that withdrawn?
MR. THORNBURGH: I'll withdraw it.
MR. HUTCHINSON: All right.
Q (By Mr. Thornburgh) You understand that their conclusion is that this cracked degraded layer that they see on the surface of the fiber, the outer layer of the fiber, is degraded polypropylene because they can see the blue dye particles within the cracked layer?
A Correct. Correct. Can I answer the question?
Q Do you disagree --

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MR. HUTCHINSON: Actually, yeah, you can answer the question, so finish answering the question.
MR. THORNBURGH: I said, "Do you understand that," and he said, "Yes."
MR. HUTCHINSON: Hey, Dan, the witness is going to finish answering his question. Go, Dr. MacLean.
THE WITNESS: Yes, I understand. However, we have clearly demonstrated they use polarized light here. You can actually see they've got -- labeled it "polarized light." If you view these microtome images with polarized light, you can create the exact same artifact, artificial artifact, artificial false bark as what they're describing there. You can see hue changes and you can see this shadowing effect that takes place that gives appearance of a bark layer. So we have proven that, yes, they could have misinterpreted those artifacts for something that really wasn't there.
MR. THORNBURGH: Well, that's not --
MR. HUTCHINSON: I'm sorry. Are you

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finished?
THE WITNESS: I'm finished.
Q (By Mr. Thornburgh) Well, they also found that there was a corresponding loss in tensile strength.
A I just explained to you that when you plasticize things -- let me take you to my report because I spelled it out in stage there.
On page 43 of my report, I take the reader through an original material that's not plasticized, in terms of its tensile properties, to a typical plasticized polymer in the -- in the figure below it.
And I've noted three things that we've been talking about all day: an increase in ductility/toughness, a reduction in modulus, which was the initial slope of those curves, and a slight reduction or a modest reduction in decreased -- or a decrease in breaking strength. So I'm telling you right here that the loss in tensile strength that you keep describing is accounted for by the material being plasticized.
Q What plasticized it? What -- how do you -- what evidence do you have that the material that these scientists at Ethicon were looking at had plasticized?

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A Dr. Jordi proved it in the Bellew data. He proved it beyond any doubt with his pyro-MS data that he was able to pull out aliphatic ester molecules from the mesh. And we know basic fundamental polymer science is that those molecules will plasticize -- will plasticize Prolene and polypropylene.
Q How do they plasticize polypropylene?
A They get inside of the polypropylene matrix or the Prolene polymer matrix and they act as a local lubricant, so polymer chains can now slide past one another readily, and that is basically a softening of the material. And that's exactly what we see here as a result of -- the physical properties that we see are a direct result of that mechanism.
Q Did you do any tensile testing of the intentionally oxidized Prolene samples that you looked at?
A We did not pull them in tension, correct.
Q Why not?
A Didn't have to. That wasn't part of our study.
Q Did you do any GPC analysis to see if there's a loss in molecular weight?
A No.

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Q One of the documents you discuss -- well, has -- Ethicon was continuing to do internal studies where their scientists were concluding that the mesh had -- the explanted Prolene had degraded, right?
A Yes, despite the data to the contrary.
Q And outside of Ethicon, there were independent scientists who were also analyzing mesh explants or Prolene or polypropylene explants, correct?
A Yes, there was mesh studying going on outside of Ethicon.
Q Celine Mary, have you reviewed her publication?
A I have.
Q Do you recall what specimen was analyzed by Mary and her colleagues?
(Exhibit 22 marked for identification.)
Q (By Mr. Thornburgh) I'll show you. See the "Materials" section on the bottom right-hand corner of the article?
A Yes.
Q Okay. And it says that they analyzed PVDF sutures and Prolene sutures manufactured by Ethicon, right?
A Correct.

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Q And they implanted them in dogs and they explanted them at two intervals, Year 1 and Year 2?
A Correct.
Q They performed FTIR analysis, right?
A They did.
Q They performed scanning electron microscopy analysis, right?
A Yes, there are SEM micrographs in the literature.
Q They did histology, a histology study; is that right? I think it's just discussing the cleaning process, right?
A Yes, they did a histological study.
Q And in their FTIR analysis where they looked at mesh explants -- well, strike that.
If you turn to page 202, again, this is Prolene, this is the same material in the TVT device, right?
A That's what it says; it says Prolene.
Q Same material that was tested by Jongebloed and the same material that Ethicon's internal scientists have been studying this entire time, right?
A That's what's reported.
Q And Mary and her colleagues found that,

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"After one and two years of implantation, the surface of retrieved and cleaned PVDF sutures did not appear to be substantially modified. In contrast, the polypropylene sutures explanted one and two years postoperatively showed evidence of surface deterioration, characterized by uniformly spaced circumferential cracking and peeling and flaking of the polymer material in the outmost surface layer," right?
A Correct. All visual observations of just cracking, correct.
Q And what -- what's your opinion that was observed -- what were they observing here of this material that was cracking and peeling and flaking off of the surface of the Prolene?
A What is my opinion of what?
Q Yeah. Do you have an opinion as to what these scientists were observing in 1996 -- or 1998 during the one- and two-year explant studies?
A That they see an outer layer that has cracks in it.
Q And they concluded that that cracked outer layer was degraded polypropylene, right?
MR. HUTCHINSON: Object to form.
THE WITNESS: Correct.

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Q (By Mr. Thornburgh) Degraded Prolene?
A Correct, again, based on this premise that the carbonyl functionality is only indicative of oxidation.
Q If you turn the page, it says, "It has been known that polypropylene is susceptible to degradation by several different initiation phenomena, including thermal, mechanical, photochemical, radiation, biologic" --
A I'm sorry, where are you?
Q On page 203. Strike it. I'll withdraw that question.
A Okay.
Q So do you disagree with -- you disagree with their conclusions, right? If you look at the "Conclusions" section, "Visual evidence of surface degradation was observed at one and two years for the polypropylene," which was the Prolene, "but not the PVDF sutures"?
MR. HUTCHINSON: Object to form, compound question.
Q (By Mr. Thornburgh) "This stress cracking phenomenon is believed to be associated with the distinct skin-core two-phase structure of oriented

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polypropylene monofilaments" --
MR. HUTCHINSON: I'm sorry, Dan, are you finished?
Q -- "and points to the likelihood of PVDF having superior biostability to Prolene" -- "to polypropylene over the long term." Do you disagree with those conclusions?
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) The conclusion is that the polypropylene, the Prolene, had degraded after one and two years, right?
A Correct, and --
MR. HUTCHINSON: Object to form.
THE WITNESS: They're making that assessment, they're drawing that conclusion based on visual observations. I can't look at a fiber -- I can't look at any material and, just because it's cracking, say it's degraded. We've talked about that all day long.
Q (By Mr. Thornburgh) Well, they also did scanning electron microscopy.
A Correct. It's the same -- it's the same argument.

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Q And they found 1740 carbonyl band.
A Right, which we've talked about all day, that there are other reasons why that peak can show up. And moreover, that peak shows up in the seven-year dog study at seven years, and we know it has no net effect on the bulk physical properties.
So it completely contradicts what they're saying here. They're saying that oxidation of polypropylene or Prolene translates into reduction in material properties. The seven-year dog study completely refutes that. We have the carbonyl peak in that -- in that study at seven years. We have the same micrographs with all the transverse grafting, and the physical properties are well within intact. As a matter of fact, they're getting better.
So you can't marry those two things, you can't marry those two concepts and say it's degraded, but yet my properties are being maintained or improved.
Q Well, scientists outside of Ethicon have been studying the loss of the tensile strength in degraded -- in explanted polypropylene, including Prolene, and had found that there was significant tensile strength --

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A There's no --
MR. HUTCHINSON: I'm sorry. Objection. Compound question.
Q (By Mr. Thornburgh) You -- I mean, you've seen -- I mean, if you look at --
A There's no --
MR. HUTCHINSON: I'm sorry. Hey, guys, stop it.
Q (By Mr. Thornburgh) If you look at the Mary article --
MR. HUTCHINSON: Dan, did you withdraw that last question?
MR. THORNBURGH: Yeah.
Q (By Mr. Thornburgh) If you look --
MR. THORNBURGH: Yes.
Q (By Mr. Thornburgh) If you look at the Mary article again, if you look on page 203, "In recent in vitro and in vivo studies, we have examined the physicochemical properties, ease of handling, and biocompatibility of a new vascular suture made out of PVDF. Compared with polypropylene, the PVDF monofilament suture showed better long-term stability in vitro by retaining 92.2 percent of the initial tensile strength over a nine-year period, whereas

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polypropylene retained only 53.4 percent." That's -- what is --
MR. HUTCHINSON: Sorry. Is that a question?
THE WITNESS: Is that a question?
Q (By Mr. Thornburgh) I mean, that's -- so these scientists outside of Ethicon have found that the property -- the properties do change and the tensile strength does decrease in explanted degraded polypropylene sutures.
A Show me the allegation where somebody is saying loss in tensile strength is causing these methods to be defective.
MR. HUTCHINSON: All right, guys, I want to ask the videographer how long we've been on the record.
MR. THORNBURGH: I've got one minute it says.
MR. HUTCHINSON: No, I'm asking the videographer.
THE VIDEOGRAPHER: I have to add it up and we'll waste time doing it.
MR. HUTCHINSON: Okay, you've got one minute?

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MR. THORNBURGH: I'm going to ask two -- yeah, I'm just --
MR. HUTCHINSON: Okay.
MR. THORNBURGH: I'm not going to --
Q (By Mr. Thornburgh) So you also -- in your report, you disagree with the findings of Clave, right? There you are, right there, 24.
A I don't -- I --
MR. HUTCHINSON: I'm going to object to the form to the extent that the findings of Clave is unclear.
Q (By Mr. Thornburgh) The conclusions of Dr. Clave that the explanted -- the -- strike that.
You disagree with the conclusions by Clave and his colleagues --
A I don't. Let's be --
Q -- that the mesh that was explanted from these women had degraded, mesh explants?
A Let's be clear about this.
MR. HUTCHINSON: Object to form.
THE WITNESS: I disagree with his use of degradation because he's again ascribing it to the fact that he just sees cracking. And we've already talked about the fact that just

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because you see cracking doesn't mean that the underlying polymer is degraded.
And secondly, if you look at his ultimate conclusion, is that he was not able to determine either way whether the material was truly oxidizing. So -- and that is in lockstep with what I'm telling you, is that there are other reasons why these carbonyl functional groups may be present aside from oxidation.
He realizes that and that's why he's very careful. There have been people that have taken his literature and taken his findings out of context and saying it's degrading, it's oxidizing. He did not say that, if you read that document properly.
Q (By Mr. Thornburgh) In the Costello --
MR. HUTCHINSON: Dan, is this the last question?
MR. THORNBURGH: Last question.
Q (By Mr. Thornburgh) In the Costello article, the Costello publication, "Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient," you've analyzed

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that, right?
A I have.
Q And I'm trying to understand what your --
MR. HUTCHINSON: Last question.
Q (By Mr. Thornburgh) Is your opinion that -- maybe it's both. Is your opinion that Costello is wrong in his analysis that these -- that this polypropylene material degraded, or is your opinion that this polypropylene material degraded but it wasn't Prolene?
A Well, let's start -- let's go backwards. There's certainly no -- there's certainly no indication that he's testing Prolene, so I think -- I guess we can short-circuit this. Whatever conclusions he's drawing on his polypropylene, we can't say carry over one for one with the Prolene material.
Q Doctor --
MR. HUTCHINSON: Dan, that was your last question. Do you have one more? I'll do it as a courtesy to you. I'll allow you one more question, and then that's it.
Q (By Mr. Thornburgh) We've gone through a lot of publications. We've gone through a lot of internal documents. Is it a fair summary of your opinions that

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the peer-reviewed publications that we've reviewed, Clave, Costello, Mary, that those peer-reviewed publications that we've reviewed, the authors in those studies reached conclusions that were incorrect or wrong because they somehow misunderstood the behavior of Prolene material in the in vivo environment?

MR. HUTCHINSON: Object to form.

THE WITNESS: I would say that there's a -- there's a couple of issues with how you just tried to summarize it. Let me try to clean it up.

First of all, we just talked about Clave, and there's nothing in his journal article ultimately that is inconsistent with I've been telling you in terms of other reasons why the carbonyl formation -- carbonyl functionality could be present.

As for the other pieces of literature, many of them don't take on Prolene, the specific composition and formulation of Prolene, in their studies. So you need to be careful with that data.

And the one that does mention Prolene -- I think it was the Wood article. You know,

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we just talked about that. And she focuses in on the visual observations of cracking and equating that -- wrongfully equating that to degradation and then simply keying on the carbonyl functionality as evidence of oxidation, which we've talked about is not the sole reason you would have a carbonyl present in the IR spectra.

So that's my summary of those four.

Q (By Mr. Thornburgh) The internal documents --

MR. HUTCHINSON: Dan --

MR. THORNBURGH: Just real quick.

MR. HUTCHINSON: Dan --

Q (By Mr. Thornburgh) What is your disagreement --

MR. HUTCHINSON: Dan --

Q -- with the internal Ethicon scientists?

MR. HUTCHINSON: Excuse me, Dan. Is this your last question?

MR. THORNBURGH: Yeah. I'm just trying to --

MR. HUTCHINSON: Now why should I believe you?

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MR. THORNBURGH: This is it.

MR. HUTCHINSON: Okay. You promise?

MR. THORNBURGH: I'm just trying to summarize this -- yep, promise.

Q (By Mr. Thornburgh) What's -- so we've talked about the outside scientists, the external scientists who published -- who published their research. But what about the internal Ethicon scientists, what is your disagreement with their conclusions from 1983 up until '87, at least -- or, sorry, '92, that the Prolene degraded in vivo?

MR. HUTCHINSON: Objection. Overly broad, compound.

THE WITNESS: You just have to look at the totality of the data, and maybe nobody at Ethicon had ever done that, looked at the big picture and pulled all the data in and synthesized it perhaps to the extent that I did. When you look at it, at the very at the end of the day, molecular weight is not changing. So therefore, by definition, we are not having bulk physical property degradation or bulk physical property -- bulk polymer degradation. Excuse me.

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And then all of the key physical properties that you want for this mesh, in terms of being flexible and in terms of being pliable and having a lot of ductility and stretchiness to it, if you will, are all being maintained and improved.

So like I said before, this carbonyl that everyone has been focusing on, at the end of the day, it doesn't matter because you've got a -- you've got a material and you've got a mesh that's maintaining or improving all of its key physical properties after seven years.

Q (By Mr. Thornburgh) In the dog study?

MR. HUTCHINSON: Dan, that's it. I'm holding you to your promise. We'll take a quick break and then I've got some questions.

THE VIDEOGRAPHER: We are now going off the video record. The time is currently 7:11 p.m.

(Recess taken.)

THE VIDEOGRAPHER: We are now back on the video record. The time is currently

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7:20 p.m.

EXAMINATION

BY MR. HUTCHINSON:

Q Dr. MacLean, my name is Chad Hutchinson. I'm counsel for Ethicon. I have a couple of follow-up questions for you.

You were asked by Mr. Thornburgh questions about polypropylene and your prior work experience with polypropylene. Do you remember those questions?

A I do.

Q Tell us about your academic studies about polymers.

A Sure. So I have two advanced degrees in polymers, one at the master's level, one at the doctor's -- doctorate level. Both of those advanced degrees, my chosen field of study was polymers, which would include -- a subset of that would include thermoplastic materials, which is what polypropylene is. So I've studied the -- at the academic level, I've studied the structure, property, synthetics, the chemistry of that material, as well as sister polymers to polypropylene.

Q And when you say "sister polymers," what do you mean by "sister polymers"?

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A I'm talking about linear thermoplastic materials. That can be -- some of them can be semi-crystal and some of them can be amorphous. We've heard terms like ABS, polycarbonate, nylon, polyester, polyethylene, polypropylene. Those are all thermoplastic polymers.

Q And have you studied the synthesis of polymers?

A I have.

Q Have you studied the manufacture of polymers?

A I have.

Q Have you studied the performance of polymers?

A I have.

Q And does all that work describe your -- strike that.

Does all that work you describe relate to polypropylene?

A It does.

Q How so?

A Well, because polypropylene, again, is one of the many materials in the engineering thermoplastic category, and the basic prevailing structure property relationships would apply to polypropylene and all the other sister polymers that I just talked about.

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Q And when you talk about the prevailing structure property relationships, tell us what you mean by that.

A Well, if you look at the molecular architecture of the polymer molecule, it gives you -- just by looking at it, it gives you a sense of what its physical properties will be in terms of its melt temperature, its glass transition temperature, what type of mechanical properties I might be able to afford from it.

Some of these sister polymers that we've talked about are aromatic, they're bigger, they're bulkier in structure, they give you more strength and more stiffness. Whereas polypropylene is a fairly linear, nonaromatic, it's called an aliphatic polymer, and it has its physical properties based on its structure.

Q Dr. MacLean, what is a nonlinear arophatic [sic] polymer?

A I'm sorry, I missed your question.

Q A nonlinear --

A Aromatic?

Q -- aromatic polymer.

A Well, an aromatic polymer is something that

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has benzene rings in it. We've all seen those six-sided hexagons in some of these chemical structures. That gives the backbone of the polymer some additional steric hindrance and some additional size and bulk, and that translates into bulk physical properties. Polypropylene doesn't have those structures and therefore has its own set of unique properties.

Q Why doesn't polypropylene have those structures?

A Based on the way it's synthesized, just based on the way the monomers are chosen to make those particular polymers.

Q Dr. MacLean, tell us about your prior work of analyzing polypropylene in different applications.

A Yeah, sure. There are several polypropylene applications that I've analyzed. And again, some of this work is proactive, some of this work is reactive, failure analysis, root cause investigations. I've been working on one project right now for the last few years involving polypropylene in pressure vessels. So this would be another glass-filled material that we talked about earlier, has a polypropylene base resin, and there's actually potable chlorinated water on the

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inside of these vessels. And one of the mechanisms that we were on the lookout for as a potential degradation mechanism is oxidation due to the chlorine environment in the water. There are other -- there are other examples, as well, with polypropylene.

Q Have you done any FMEA analysis?

A Sure.

Q What does that mean?

A That stands for Failure Modes and Effects Analysis.

Q And have you done, Dr. MacLean, any failure modes analysis of polypropylene?

A I've done failure modes and effects analysis on a number of different polymer systems, yes, or a number of different components made out of polymers, which would include polypropylene.

Q And give us an example of that, please, sir.

A Well, we're doing one, actually, right now. We have a client that makes high-end plastic chairs out of polypropylene. It's a calcium-filled polypropylene material. It is -- some of their chairs are underperforming in the field, and we're trying to use the FMEA technique to understand why those failures are occurring.

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Q Dr. MacLean, have you studied the degradation modes of the polymers that you're familiar about over the last few years?

A I have.

Q And what are degradation modes?

A Well, we talked about degradation all day long, which is the physical breaking down of the polymer chains, and there's a number of different mechanisms that can get you there.

Q Can you give us an example, please?

A Sure. Well, we've talked about oxidation all day long. That is one mechanism where you can have energy coming into the polymer. In some cases, that energy can be UV. You can have chemical energy coming in from a chemical environment. You can have energy coming in from thermal or heat environments.

All of those energies coming into the polymer will break the polymer backbone; and if oxygen species are available, they will attach on to the polymer backbone and cause the oxidation that we've been talking about.

Q And have you studied those degradation mechanisms?

A I have. And there's other ones that I haven't gotten to yet.

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Q I'm sorry.

A No, that's okay. So another degradation mechanism could be just thermal degradation, just too much heat and chains break down. Another degradation mechanism, or a cracking mechanism, I should say, is environmental stress cracking, which I've studied extensively.

Q And, Dr. MacLean, are those degradation mechanisms relevant to the work that you have done in this litigation?

A They are.

Q Why?

A Well, they've -- my knowledge with ESC -- and just let me make sure I'm clear on that. That is not a chain scission, that is not a chemical degradation process. That is a physical process like we've talked about all day long. But I've done extensive work with ESC, and that experience and training has led me to the determination that there's not ESC taking place in these fibers.

Q You were asked questions about whether you have ever analyzed an explanted piece of mesh. Do you remember that question?

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A I do.

Q Have you?

A I have not.

Q Why not?

A I didn't think I needed to.

Q Would that be necessary in reaching your opinions in this litigation?

A No. Because as we've talked about all day long, to get to the data that you need to make these determinations on whether oxidation is taking place or some other mechanism is taking place, you have to take these samples and analyze them with instrumentation. And you're looking at surface layers and other physical aspects that are on the microscale, and you just can't pick up -- you can't make any of those determinations with just putting it in this your hands or visualizing it with your unaided eye.

Q Would it be duplicative?

A It would be duplicative because this whole matter is data -- what I call data rich.

Q And what do you mean by "data rich"?

A There is data everywhere you look in terms of molecular weight data, melting point data, strength, elongation, modulus data. The list goes on and on.

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FTIR data, et cetera. So there's plenty of data that's been generated that can be synthesized and reviewed.
Q Would it be necessary to examine or analyze an explanted piece of mesh in order to reach the opinions you have in this litigation?
A No.
Q For the reasons we discussed?
A For the reasons we discussed.
Q You were asked questions about publishing peer-reviewed literature about polypropylene.
A Correct.
Q Do you remember that?
A Yes.
Q Dr. MacLean, have you published peer-reviewed literature about sister polymers?
A I have.
Q Is that relevant to a discussion about polypropylene polymers?
A It is.
Q How so?
A Like we just talked about, I mean, all of these degradation mechanisms, the analytical tools that everyone has used, the quantification of bulk mechanical properties, et cetera, those will translate

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to all of the other polymers that we've talked about, including polypropylene.
Q Let's switch gears for a minute, okay?
A Sure.
Q You were asked questions by Mr. Thornburgh about whether lab notebooks were prepared in accordance with GLP, or good laboratory practices. Do you remember that line of questioning?
A I do.
Q Did you personally prepare lab notebooks?
A I did not personally prepare a lab notebook.
Q Why not?
A Because it was done for me at the -- at my direction by Ms. Benight -- or Dr. Benight and the Histion lab.
Q Is that common practice?
A It is.
Q When you were asked whether you personally kept a lab notebook for staining experiences -- experiments, what did you understand that question to mean?
A I thought --
MR. THORNBURGH: Objection.
THE WITNESS: I thought that question

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was directed at me personally, not at the body of work that we did.
Q (By Mr. Hutchinson) Did Dr. Benight maintain lab notebooks?
A She did.
Q Is it common practice for Dr. Benight to maintain lab notebooks?
A It is.
Q Are those lab notebooks that Dr. Benight maintained in the file that was generated and given to the plaintiff's lawyer before the deposition?
A It was.
Q And is that Exhibit 5 that is the flash drive?
A Correct.
Q And did you give Exhibit 5 to the plaintiff lawyers before this deposition started?
A I did.
Q And how many plaintiff lawyers have been here during your seven hours of deposition?
A There are two.
Q Did those two plaintiff lawyers have the opportunity to review the flash drive that you gave them before this deposition started?

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A They --
MR. THORNBURGH: Objection. Argumentative. With all due respect, you handed me a flash drive as we're doing the deposition that contains hundreds of material.
Q (By Mr. Hutchinson) You can answer.
A We've been -- I've been being deposed with breaks for the last seven-and-a-half hours.
Q Okay. Did you confirm that the Histion quality control documents are in your file?
A They are.
Q And have those files been given to the plaintiff lawyers?
A They have.
Q What is the Histion lab?
A It is the lab that we used to perform the histological staining that we've talked about.
Q And have you used the Histion lab before?
A Exponent has, yes, on several occasions.
Q Why?
A Because that is their expertise.
Q Did the Histion lab follow its internal quality control procedures when it performed the sample

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preparation?
A They did.
Q What about the sample embedding?
A Same answer, they did.
Q Microtoming?
A Yes, they did.
Q Staining procedures?
A Yes, they did.
Q Dr. MacLean, do we have traceability between the mesh used for the testing, the samples that were prepared and stained, and the results that were generated?
A Yes, we do.
Q How do you know that?
A Because it's all in the documentation and it's all with the file structure that we've created on the folders.
Q Would that be the same documentation that has been given over to the plaintiff lawyers?
A It has.
Q Represented in Exhibit 5?
A That is correct.
Q Dr. MacLean, does the proper documentation exist so that another scientist could repeat and verify

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your work?
A Yes, absolutely.
Q Dr. MacLean, have you maintained and preserved all the samples from your testing?
A We have.
Q Let's talk about the SEMs for just a minute that were done by Exponent on the oxidized samples, okay?
A Correct.
Q Do you have an electronic version of the lab notes that correspond to the work that was done?
MR. THORNBURGH: Objection.
THE WITNESS: Sorry, could you repeat that?
MR. HUTCHINSON: Yeah.
Q (By Mr. Hutchinson) Do you have an electronic version of the lab notes that correspond to the work that was done?
A We have one-to-one correspondence between the micrographs that we took and the samples that they came from.
Q And what does "one-to-one correspondence" mean to you?
A We can trace back from the actual fibers that

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were either chemically or UV oxidized all the way through to the microtome samples that were stained and imaged by optical microscopy.
Q Why is -- is traceability important --
A It is.
Q -- to a -- excuse me. Is traceability important to a scientist like yourself?
A It is.
Q How so?
A For the very reasons we talked about. If someone wanted to re-create your work and verify it, you would want to have that traceability. If you wanted to go back and look and examine these things a second or third time with a fresh set of eyes, you would have that traceability.
Q Dr. MacLean, let's talk about -- let's switch gears for a minute. You were asked early on in your deposition whether or not you were an expert in chemistry. Do you remember that line of questioning?
A I do.
Q How do you define being an expert in chemistry?
A My definition is that you need to have advanced degrees, specifically in chemistry, and then

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you would have to have a significant amount of training and professional experience, as well, on top of that.
Q Dr. MacLean, are you an expert in the chemical interaction of polymers and organic material?
A I am.
MR. THORNBURGH: Objection.
THE WITNESS: I am.
Q (By Mr. Hutchinson) How so?
A Well, it's a combination of my specific organic polymer training and courses that I've taken in academia, and then in addition to the 20 plus years I've been studying these materials.
Q Is that the type of chemistry that you would use and rely on in your work as a polymer scientist?
A Yes.
Q When we talk about ionic bonds forming between two molecules, what does that mean to you?
A It means that you typically have one molecule that is either rich or deficient in electrons, and it has either a positive or negative charge associated with it, and it goes out and seeks other molecules with the opposite charge and ionically bonds.
Q Do you have to be an expert in chemistry to understand that?

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A No. That is high school chemistry. That's just an "ionic bond" definition, high school chemistry, first-year undergraduate chemistry classes.
Q Is that the type of chemistry that you work, as a polymer scientist -- is that the -- strike that.
Is that the type of chemistry that you use in your practice as a polymer scientist at Exponent?
A Sure. We look at ionic bonds, covalent bonds, things of that nature, correct.
Q What about hematoxylin and eosin chemical staining, are you familiar with that process?
A I am.
Q Are you qualified to give opinions about how that chemical process works?
A Yes.
Q Why?
MR. THORNBURGH: Objection.
THE WITNESS: For the reasons we just talked about. Hematoxylin and eosin are positively and negatively charged ionic molecules, and they go out during the staining process and they look for molecules with opposite ionic charges to chemically bond with, and those would be proteins that

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both carry positive and negative charges.
Q (By Mr. Hutchinson) Is this type of chemistry a basic understanding of polymer scientists?
A It is. Ionic bonding is a basic chemistry topic.
Q And if the plaintiffs argue that you cannot discuss the testing because you're a, quote -- you're not, quote -- strike that.
If the plaintiffs argue that you're not allowed -- strike that.
If the plaintiffs argue that you cannot discuss your testing because you said you're not an expert chemist, would you agree with that?
A I would --
MR. THORNBURGH: Objection.
THE WITNESS: I would disagree with that.
Q (By Mr. Hutchinson) Why?
A For the reasons we have talked about. I just -- I just explained to you the ionic bonding that needs to take place for the stain to hold.
MR. THORNBURGH: Chad --
Q (By Mr. Hutchinson) Is that --
MR. THORNBURGH: -- quit leading your

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witness, man.
Q (By Mr. Hutchinson) Is that something that a polymer scientist like yourself should understand?
A Yes.
Q Let's look at Exhibit 7 for a minute. Do you have Exhibit 7 in front of you?
A I do.
Q And if we look on maybe the sixth or seventh page in, under "Announcements," that includes a picture of yourself, correct?
A It does.
Q And were you asked questions about this paragraph?
A I was.
Q And you were asked questions about you performing litigation and nonlitigation failure analysis; is that right?
A I was, correct.
Q Do you recall being asked any questions by the plaintiffs' lawyer about assisting industry clients with product development?
A I was not.
Q Have you done that?
A I have.

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Q Have you done that for medical devices?
A I have.
Q Have you done it for polypropylene medical devices?
A I have.
Q For example, what?
A Polypropylene syringes would be one of them.
Q Did that include the addition of ingredients to the base polymer, polypropylene?
A Yes. It would -- the analysis would include the whole polymer formulation, which would include the base polymer, polypropylene, and any additives that might be put into the material.
Q Is that similar to what we've discussed today about the differences between Prolene and polypropylene?
A Yes.
Q You were asked questions about your work for other companies who were defendants in litigation. Do you remember that?
A I do.
Q Have you ever done any plaintiff expert work?
A I have.
Q You were asked questions about whether you

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reviewed explants from 37 plaintiffs. Do you remember that line of questioning?
A I do.
Q Do you know when those explants were divided among the parties?
A I do not.
Q Did the plaintiffs' lawyer tell you they were divided among the parties just days before expert disclosures were due?
A They did not.
MR. THORNBURGH: Objection. Mischaracterizes --
Q (By Mr. Hutchinson) How long --
MR. THORNBURGH: -- the events.
Q (By Mr. Hutchinson) How long does it take to clean an explant?
A It can be a long time.
Q Is cleaning an explant important?
A It can be.
Q Does it take more than two days?
A It can.
Q Why is cleaning an explant important?
A Well, you want to remove any foreign tissue or the formalin-fixed material that's on the outside of

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the Prolene.
Q Did the plaintiffs' lawyers designate some experts in this litigation?
A They have.
Q Did they designate polymer scientists just like yourself?
A They have.
Q Did they designate two polymer scientists?
A They did.
Q Who did they designate?
A Dr. Jordi and Dr. Guelcher.
Q Did Dr. Jordi and Dr. Guelcher analyze any of the 37 explants, to your knowledge, according to their reports?
A According to their reports, no, they did not.
Q I want to ask you a very quick question about the Wood article. Does the Wood article use the word "Prolene" in it?
A It does not.
Q Does the Wood article discuss Prolene?
A It does not.
Q What is the TVT mesh made up of in this litigation?
A Prolene.

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Q You testified, when asked questions about the Wood article, that there are other explanations such as FAE. Do you happen to remember that?
A I do.
Q What does FAE stand for?
A General classification of fatty acid esters.
Q What are fatty acid esters?
A They're the molecules I've talked about all day today. It's an aliphatic tail with an ester functionality at one end of the molecule.
Q Do fatty acids and esters have C double bond O's?
A Yes, they do.
Q What does it mean to have a C double bond O?
A It means that you have a carbonyl group in your molecule.
Q And what's the significance of having a carbonyl group in your molecule?
A Well, because that can be -- that peak that shows up with the ester can be in the same region as where oxidation peaks up -- peaks show up in the IR spectrum.
Q Do you recall Mr. Thornburgh asking you questions about Dr. Thames' testimony?

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A Yes.
Q Did the plaintiffs' lawyer give you a full copy of Dr. Thames' transcript?
A They did not.
Q Would you like to have seen the entire transcript before answering questions about what Dr. Thames said?
A It would have been helpful to reread portions of it, yes.
Q Did the plaintiffs' lawyer read only --
MR. THORNBURGH: Objection, leading. Come on.
Q (By Mr. Hutchinson) Did the plaintiffs' lawyer read only a portion of the transcript to you or the entire transcript?
A Just a portion.
Q Did the plaintiffs' lawyer show you any exhibits that were used with the deposition of Dr. Thames?
A No.
Q Let's change gears for a minute, and I want to ask you a couple of questions about antioxidants, okay?
A Okay.

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Q And specifically I want to ask you questions about primary and secondary antioxidants.
A Okay.
Q Does Ethicon put antioxidants in polypropylene to make Prolene?
A They do.
Q What are the names of the two antioxidants that they use?
A They use Santanox R and DLTDP.
Q Okay. Which one is a hindered phenol?
A The hindered phenol is Santanox R.
Q What is a hindered phenol?
A It's a bulky -- excuse me, a bulky molecule that actually goes out and scavenges free radicals.
Q What is a thioester?
A A thioester is a secondary antioxidant.
Q What is -- in this litigation, is DLTDP what you would consider a thioester?
A It is.
Q What does it mean to be a thioester?
A It means it goes -- that molecule goes out and searches for peroxide-type molecules and neutralizes them so they can't cause damage to the underlying polymer.

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Q The plaintiffs' lawyer asked you questions about what Dr. Barbolt said in his deposition testimony. Do you remember that?
A I do.
Q Were you shown the full transcript of Dr. Barbolt?
A I was -- I was not.
Q Did the plaintiffs' lawyer read selective pages of Dr. Barbolt's transcript to you?
A Yes.
Q Do you remember the plaintiffs' lawyer asking you about page 409 --
A I do.
Q -- of the transcript?
A I do.
Q Did the plaintiffs' lawyer show you 408 other pages of the transcript?
A They did not.
Q Did the plaintiffs' lawyer show you any exhibits that were used with Dr. Barbolt?
A They did not.
Q Did the plaintiffs' lawyer show you any follow-up questions that Ethicon's lawyers asked of Dr. Barbolt?

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A No.
Q Do you know how many days Dr. Barbolt was deposed?
A I do not.
Q Did the plaintiffs' lawyer show you one day or two days of his deposition?
A I don't recall.
Q Let's look at Exhibit 10 for me.
A Okay.
Q Are you there with me?
A I am.
Q Do you remember the plaintiffs' lawyer asking you questions about this document?
A I do.
Q Let's look at the third paragraph, first sentence. It says, "Polymer degradation is a natural phenomenon that cannot be totally stopped." Do you see that?
A I do.
Q Did I read that correctly?
A You did.
Q Do you remember the plaintiffs' lawyer asking you questions about that paragraph?
A I do.

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Q Dr. MacLean, have you seen any evidence in this litigation that Prolene mesh degrades in the body over the lifetime of the patient?
A I have not.
Q Dr. MacLean, you were asked questions earlier about whether or not you did any GPC analysis. Do you remember that question?
A I do.
Q What does GPC stand for?
A Gel permeation chromatography.
Q Did you do any gel permeation chromatography to determine loss of molecular weight?
A I did not.
Q Why not?
A For my experiments, it was not necessary.
Q Why wasn't it necessary?
A Because my experiments were focused on determining whether oxidized or unoxidized Prolene would actually stain in H&E staining.
MR. HUTCHINSON: Let's go off the record. I think I'm about done.
THE VIDEOGRAPHER: We are now going off the video record. The time is currently 7:47 p.m.

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(Recess taken.)
THE VIDEOGRAPHER: We are now back on the video record. The time is currently 7:49 p.m.
MR. HUTCHINSON: Dr. MacLean, I don't have any more questions. Thank you for your time.
THE WITNESS: Okay. Thank you.
FURTHER EXAMINATION
BY MR. THORNBURGH:
Q All right, Doctor. Doctor, what is hematoxylin stain?
A What is hematoxylin stain?
Q Uh-huh.
A It's an ionic stain that we talked about a few minutes ago that has the ability to stain charged particles, charged molecules.
Q What are some examples of some charged particles or charged --
A Well, they're in the --
Q -- molecules?
A -- they're in the report. There's proteins, amino acids, polypeptides. All of them that are found naturally in the body have ionic charges to them.

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Q Is it your understanding that hematoxin [sic] --
MR. HUTCHINSON: Hematoxylin.
Q -- hematoxylin stains extracellular proteins?
A It stains a specific protein with a negative charge.
Q What about extracellular proteins?
A It would depend on the charge.
Q What about cell membranes? Doctor?
A Yeah, I want to give you an answer that's correct.
Q Can you tell me off the top of your head?
MR. HUTCHINSON: No, Dan, we're not doing that. He's -- the witness has told you he's trying to give you an answer that's correct.
Q (By Mr. Thornburgh) You still need some time, Doctor?
A Yes, I do.
No, eosin is the proper staining mechanism for cellular membranes.
Q You said -- what did you say? I'm sorry.
A Eosin.
Q So it's your -- it's your opinion that

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hematoxylin does not stain cell membranes, correct?
A According to my research, eosin stains cellular membranes. Cellular membranes have a positive charge, and eosin is a negatively charged ion.
Q Does it stain cytoplasmic components?
MR. HUTCHINSON: Object to form.
THE WITNESS: Eosin does.
Q (By Mr. Thornburgh) Okay, not hematoxylin?
A If it has a negative -- if it has a negative charge, if the ion that it's seeking out has a negative charge, hematoxylin will be the compound that will stain with it. If it's seeking something that has a positive charge, eosin will be the staining element that will stain that --
MR. THORNBURGH: We've got to change the tape.
A -- biological material.
MR. THORNBURGH: We have to change the tape.
THE VIDEOGRAPHER: We are now going off the video record. The time is currently 7:52 p.m. This is the end of Tape No. 6.
(Off the record.)
THE VIDEOGRAPHER: We are now back on

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the video record with Tape No. 7. The time is currently 7:55 p.m.
Q (By Mr. Thornburgh) Doctor, before we went off the record, we were talking about the types of biologic material that is stained by hematoxylin. Does hematoxylin stain nuclei? Can you tell me without looking at the report?
A I can. It does.
Q What about DNA -- or, sorry, strike that.
What about amino acids?
A It depends on the charge in the amino acids. There can be amino acids that have positive charges, there can be amino acids that have negative charges, and their respective staining element will take care of the positive or negative ionic bonds that are in those amino acids.
Q What is the role of mordants in the histological stains?
A It's a bridge for hematoxylin.
Q A bridge -- can you explain that a little bit?
A Sure. So hematoxylin converts to hematin, and then you need the mordant from hematin to actually cause the ionic bond to take place, which is a positive

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charge, the cation, to actually wind up combining with a negative molecule, negatively charged molecule that it's trying to stain.
Q Is polypropylene charged?
A It is not. It's not ionically charged.
Q What is it charged by?
MR. HUTCHINSON: Object to form.
THE WITNESS: It's not charging anything. I'm just trying to stay within the confines of staining, ionic staining. And polypropylene, nor oxidized polypropylene, and Prolene and oxidized Prolene, none of them are ionic in nature.
Q (By Mr. Thornburgh) Do you have any references that you rely on for that?
A It is fundamental polymer science that those are not ionic molecules.
Q Is it your -- I'm trying -- I'm just trying to understand your opinions. Is it your opinion that substances only possess -- substances that only possess a charge can stain?
A An ionic charge. It has -- it's seeking out molecules that are either in surplus or are deficient with electrons. And polypropylene, as a molecular

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structure, is not deficient in electrons, nor does it have a surplus of electrons in its -- in its neat state, N-E-A-T, state.
Q Do you routinely use histological staining?
A I do not.
Q When was the last time, other than this case, that you asked for or ordered some H&E staining to be done of explanted specimens?
A This was the first time that I've actually done that, and that's exactly why we went to a third-party lab that specializes in it.
Q Defense counsel asked you or discussed with you questions I asked or -- strike that.
Defense counsel asked you whether I had only read an excerpt of Dr. Thames's deposition testimony. Do you recall that?
A I do.
Q Defense counsel had an opportunity to correct any perceived misinformation or inaccurate information on direct examination, but he didn't ask you a single question or show you a single excerpt from the Thames deposition transcript, did he?
A He did not.
Q Same with Dr. Barbolt, he had an opportunity

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to show you some transcript testimony from Dr. Barbolt to demonstrate that somehow I had misled you or misrepresented something to you, but he did not ask you or show you any transcript testimony from Dr. Barbolt, did he?
A He did not.
Q When was the last time you actually performed GPC analysis?
A Me personally or used it as a tool in one of my investigations?
Q You personally.
A Personally was probably in graduate school. But I've used that tool for the last 20 years in polymer investigations.
Q When was the last time you cleaned -- strike that.
When was the last time you dissolved tissue from an explanted medical device, in other words, cleaned it with some type of reagent?
A I have not -- I have not cleaned tissue from an explanted medical device.
Q When was the last time you performed DSC testing?
A Personally?

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Q Yes.
A Again, probably in graduate school is when I last ran the instrumentation. I run DSC on polymer samples, you know, weekly -- weekly and monthly, rather.
Q When was the last time you performed FTIR analysis outside of this case?
A Probably the same answer. Probably graduate school when I last had my hands on the instrumentation. And again, that's a technique that -- and a tool that we use in polymer science on a weekly/monthly basis on all of our investigations.
Q And graduate school was 18, 20 years ago?
A No, no.
Q Fifteen years ago?
A 2004 through 2007.
Q Now, defense counsel had represented that the division of certain TVT explants occurred right before expert disclosures were due. You have no idea when expert disclosures were due, correct?
A I have no idea.
Q You have no idea and didn't know that the plaintiffs' disclosures were due before the plaintiffs' -- before the defendant's disclosures were

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due right around the time of the division, you had no idea about that, right?
A I had no idea.
Q And do you understand that Dr. Ong, an Exponent employee, an expert in mesh litigation, is the doctor that actually went up to Toronto and divided the TVT meshes?
MR. HUTCHINSON: Object to form.
THE WITNESS: I'm not aware of that. I'm not aware of that.
Q (By Mr. Thornburgh) And Dr. Ong is your colleague, right?
A He is my -- he in an Exponent employee, correct.
Q You know Dr. Ong, right?
A I know him.
Q He doesn't live -- he practices out of the Philadelphia office. You're in the, what, Maryland office?
A My office is in Bowie, Maryland, correct.
Q How far is -- that's a -- that's a train ride, right?
A You can -- you can travel it by train.
Q And Dr. Ong didn't reach out to you and ask

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you if you could conduct -- strike that.
Defense counsel, Chad or other lawyers for Ethicon, never reached out to you to ask you if you could conduct either the cleaning of the mesh TVT specimens or the analysis of the TVT specimens, correct?
A No one reached out to me to do that work, correct.
Q This is despite the fact that Dr. Ong, your colleague at Exponent, did the division?
A As reported by you.
Q Have you looked at the expert report of Dr. Thames?
A In this matter?
Q Yes.
A I have not.
Q And you know Dr. Thames is in Mississippi, right?
A I do.
Q So Dr. Ong shipped the mesh TVT specimens from Philadelphia to Jackson, Mississippi; is that your -- that's where Dr. Thames lives?
MR. HUTCHINSON: Object to form.
THE WITNESS: I have no idea if any

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goods were transferred. I have no idea about that.
Q (By Mr. Thornburgh) Defense counsel asked you --
(Interruption in the proceedings and discussion off the written record.)
Q (By Mr. Thornburgh) Defense counsel asked you about -- asked questions that I had asked you about, and he said, "Do you remember when Mr. Thornburgh asked you if you ever represented -- or have ever been retained as an expert on behalf of plaintiffs?" Do you remember that question?
A I do.
Q And you said yes?
A I did.
Q But when you testified -- your testimony during my cross-examination was that, yes, you had represented plaintiffs, but those plaintiffs were corporate plaintiffs, correct?
A Correct. Both of those answers are true.
Q You never represented a plaintiff who had been harmed by a corporate defendant?
MR. HUTCHINSON: Object to form.
THE WITNESS: I have not been retained

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by a firm that has been hired to represent an individual plaintiff.
Q (By Mr. Thornburgh) I looked at the Exhibit No. 5, which was the thumb drive --
A Correct.
Q -- and I still couldn't find the lab notebooks from any of your --
A It's in the -- it's in the histology folder.
Q Okay. So Dr. Beright's [sic] --
A Benight.
Q -- Benight's lab notebooks are in your folder -- are in that folder?
A Correct. There's a lab notebook -- there's an electronic version of our lab notebook as well as a log of the -- all of the micrographs that were taken.
MR. HUTCHINSON: Just let the record reflect that the receptionist has come in and advised that they're trying to turn the lights off. So, Dan, I'm going to ask that you please speed up the process if you have any more questions. Do you have any more questions?
MR. THORNBURGH: Let me just look at my notes, buddy.

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MR. HUTCHINSON: Okay.
Q (By Mr. Thornburgh) Couple more questions. I think your testimony was that the ionic bond science that you used in this case is basic science that's performed by high-schoolers?
MR. HUTCHINSON: Object to form, mischaracterizes --
Q (By Mr. Thornburgh) Or learned in high school?
MR. HUTCHINSON: Dan, we don't have time to mischaracterize testimony.
MR. THORNBURGH: I'm not. That's what the testimony is.
MR. HUTCHINSON: The receptionist has asked that we leave because they're trying to turn the lights off. So would you please rephrase.
MR. THORNBURGH: These are direct to -- these are --
MR. HUTCHINSON: Would you please rephrase your question.
Q (By Mr. Thornburgh) Your testimony, I believe, was that high-schoolers learn about ionic bonds, it's basic chemistry.

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A Ionic bonds are in basic chemistry books, textbooks, classes, et cetera, yes.
Q And when was the last time you -- when was the last time you -- did you learn ionic bonds in high school?
A Yeah.
Q Okay.
A In high school chemistry, sure.
Q Did you take college chemistry?
A I did.
Q Was that --
A Several courses in high school -- excuse me, in college-level chemistry.
Q I'm sorry, several courses?
A Several courses in college-level chemistry, correct.
Q And did those courses deal with ionic bonds of hematoxylin or eosin?
A Not specifically those two compounds, but you're talking about a bond chemistry that's just fundamental to chemistry.
Q And the reason why -- I think you testified the reason why you sent the mesh explants to this third party was because you haven't done H&E staining, right?

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A I have personally not done it, correct.
Q Do you know what's involved with the H&E staining process?
A Sure. It's listed in my report. There's a complete sequence of the H&E staining.
Q I understand that. I also know you had help with other folks at Exponent, and I'm not faulting you for that --
MR. HUTCHINSON: Hey, guys, hold on a minute.
Q -- but do you -- do you know the --
MR. HUTCHINSON: Do you have a question, Dan?
MR. THORNBURGH: Yeah.
Q (By Mr. Thornburgh) Do you -- what is the --
MR. HUTCHINSON: All right, well, state your question.
Q (By Mr. Thornburgh) What is the process that was performed or is performed in H&E staining of explanted polypropylene -- I'm sorry, of pristine degraded polypropylene mesh?
MR. HUTCHINSON: Object to the form.
THE WITNESS: I'm just going to --
MR. HUTCHINSON: Been asked and

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answered.
THE WITNESS: I'm just going to wind up reading the process that's clearly outlined in our report.
MR. THORNBURGH: Okay.
THE WITNESS: If you'd like me to do that, I will.
Q (By Mr. Thornburgh) Is that a process that you learned through this third party?
A Yes, absolutely.
Q So they -- you called them up and asked them what the process was?
A It was a bit more -- it was a bit more to it than that. We gave them the staining protocol that Dr. Iakovlev had used, and we said, "Can you create a staining process that mimics what he did," and that's what they did for us.
Q Are there different -- I'm almost done. Are there different types of H&E staining?
A There are.
Q And what are the different types of H&E staining?
A I'm not -- I'm not sure. I just know that there are different variants of hematoxylin, for

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example.
Q Do you know what variant was used by Dr. Iakovlev?
A I believe -- I believe he used a water-based, and then I believe we used an alcohol-based.
Q And what would -- do you know what the -- why -- strike that.
So you believe he used a water-based and your third party used an alcohol-based?
A That's what I believe, correct.
Q And do you know why this third party that you retained to help you with this analysis did an alcohol base rather than a water base?
A Because that's the type of -- those are the specific H&E stains that they have and they use on site.
Q Do you know what would -- could have been different had you used the same H&E staining that was used by Dr. Iakovlev?
A My understanding, there would be no difference.
Q Why do -- why do -- strike that.
Why do some labs use alcohol-based H&E staining versus water stain?

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A I think it's just a matter of what chemistry that you decide to use in your lab. All of these stains that -- these number of different stains exist. Some labs use Stain A; some labs use Stain B.
Q Did you ask this third-party lab to use the same H&E staining that was used by Dr. Iakovlev?
A I did not. We asked them if we -- if we [sic] thought it was going to have any meaningful impact on the experiment or the results, and they assured us the answer was no.
MR. HUTCHINSON: Dan, any other questions? I'd like to be courteous to our receptionist.
MR. MORRIS: Yeah, we do. Let's go off the record for two minutes.
MR. HUTCHINSON: You do have questions?
MR. MORRIS: Maybe one more.
MR. HUTCHINSON: All right, well, I want to -- I just want to make the record to reflect the receptionist has asked that we leave multiple times, and we're trying to be courteous to the receptionist.
THE VIDEOGRAPHER: We are now going off the video record. The time is currently

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8:11 p.m.
(Off the record.)
THE VIDEOGRAPHER: We are now back on the video record. The time is currently
8:12 p.m.
Q (By Mr. Thornburgh) The H&E slides that were created, were those done originally on unstained charged or uncharged slides?
A I believe the slides were charged, slightly charged. That's why you get some degree of adhesion between the microtome sample and the glass prior to putting them in the baths.
Q So yours were charged?
A I believe so.
Q Okay. And do you know what Dr. Iakovlev's were?
A I don't recall.
Q Would it impact the results if Dr. Iakovlev used uncharged stains and you used charged?
A Not that we've been advised by the laboratory.
Q Is that a question that you asked the laboratory?
A We asked them the general question, giving

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the protocol that Dr. Iakovlev had presented to us, whether there would be any meaningful differences between the two, and they assured us the answer was no.
Q What's the purpose of uncharged versus charged slides?
A What's the purpose?
Q Yeah.
MR. HUTCHINSON: Object to form.
Q (By Mr. Thornburgh) What's the significance in H&E staining of degraded polypropylene of using uncharged versus charged slides?
A I don't see how there's any significance to that.
MR. HUTCHINSON: Any other questions, Dan?
Q (By Mr. Thornburgh) And did you say that this third-party lab's protocols are all produced in Exhibit No. 5?
A Yeah, and they're also in the report.
MR. THORNBURGH: Okay, no questions.
MR. HUTCHINSON: No questions? Thanks.
FURTHER EXAMINATION
BY MR. HUTCHINSON:
Q Dr. MacLean, I have one follow-up question.

Could Dr. Iakovlev take your samples and try to stain them on his own?

A He could.

MR. HUTCHINSON: Okay. I don't have any questions. Thank you so much.

MR. THORNBURGH: Could Dr. Iakovlev take your samples and try to stain them on his own?

MR. HUTCHINSON: Yeah.

MR. THORNBURGH: I don't understand the question. How --

MR. HUTCHINSON: Okay. Well, I'm not asking you the question. Do you have any further questions?

MR. THORNBURGH: No.

MR. HUTCHINSON: All right.

THE VIDEOGRAPHER: We are now going off the video record. The time is currently 8:15 p.m. This is the end of Tape No. 7 and the end of the deposition.

(Deposition concluded at 8:15 p.m.)

C E R T I F I C A T E

STATE OF GEORGIA
COUNTY OF COBB

I, MICHELLE M. BOUDREAUX, do hereby certify that STEVEN MACLEAN, Ph.D., P.E., the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by such witness.

I further certify that I am not related to any of the parties to this action by blood or marriage and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 1st day of October 2015.

_____

MICHELLE M. BOUDREAUX, RPR

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EXAMINATIONS

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EXHIBITS

INDEX (Cont'd)

INDEX (Cont'd)

ERRATA SHEET FOR THE TRANSCRIPT OF:

Case Name: In Re: Ethicon Pelvic Repair System

Deposition Date: September 29, 2015

Deponent: Steven B. MacLean, Ph.D., P.E.

Pg.	Ln.	Now Reads	Should Read	Reason
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Signature of Deponent

SUBSCRIBED AND SWORN BEFORE ME
THIS _____ DAY OF _____ 20___.

_____

(SIGNATURE OF NOTARY PUBLIC)
MY COMMISSION EXPIRES:_____